PalmScan VF2000NEO
Visual Field Screening User Guide

010-0102-01

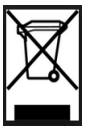
Revision A1

Medical Device Safety Symbol IEC 60417-5333: Type BF Applied part complying with IEC

60601-1 to provide protection against electric shock. The part of the device in contact with the patient is floating from earth ground.

Caution or Warning symbol

To indicate that caution is necessary when operating the device or control close to where symbols places, or to indicate that the current situation needs operator awareness or operator action to avoid undesirable consequences.



Do not dispose Medical Electronic Device in trash can. For proper electronic waste disposal, follow local governing ordinances and recycling plans regarding disposal or recycling of device components.

5V DC Charge Power 1.6A or 5V DC 500 mA USB power.

 Only Micro Medical Devices VR is Approved.

 All services shall only be performed by Micro Medical Devices and Micro Medical Devices assigned representatives.

North America

Micro Medical Devices, Inc.

23945 Calabasas Road, Suite 110

Calabasas, CA. 91302

Toll-Free Phone: 866.730.0663 Local: 818.874.0000 Fax: 818.337.1952

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1. SAFETY AND BASIC INFORMATION

1.1 Device Architecture

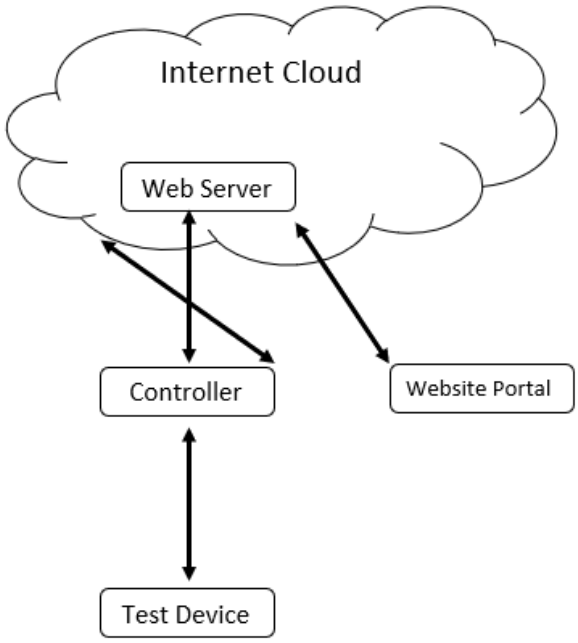


Figure 1: Tablet/Desktop Controller Device Architecture

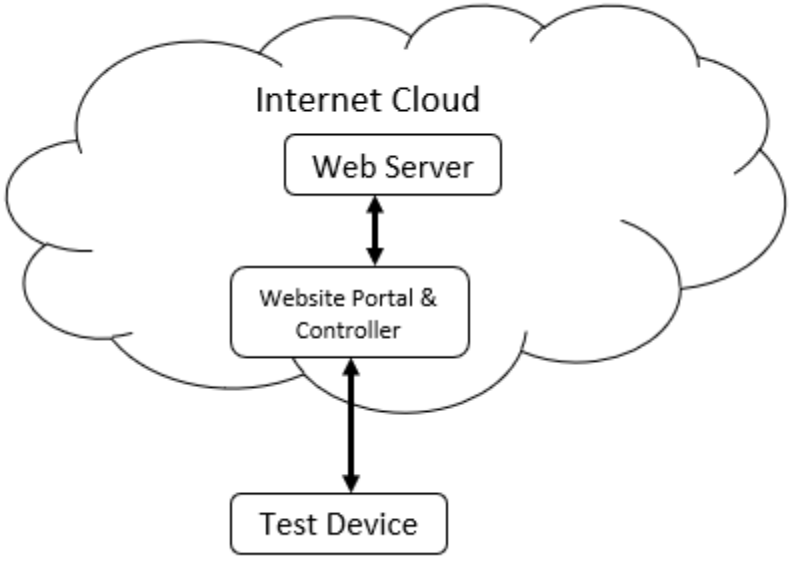


Figure 2: Web Controller Device Architecture

1.2 Introduction and Instrument set-up

This chapter is meant to familiarize the user with the following:

- The significance and unique features of perimetry
- Installation and safety precautions
- Intended use and definition of terms

1.3 Method of Operation of the VF2000NEO User Device

Figure 3: VF2000NEO Device

The Micro Medical Devices Inc. Visual Field (VF2000NEO) machine takes visual field measurements of up to 70 degrees of field of view. The office staff using the controller will connect the VF2000NEO Test Device and activate it for the selected test. The Patient will be asked to wear the VF2000NEO Test Device on their forehead. The Office Staff shall give simple instructions to the Patient on how to fixate on the Red fixation light and use the hand trigger push button for registering the responses. Here is a sample on how to train the Patient on using the VF2000NEO User Device by verbal instructions.

After giving training instruction to the Patient, the office staff will select the VF2000NEO test device(s) linked to the controller and confirm connection by clicking the patient response trigger and seeing the full connection verified appear. Add or Select Patient in the database. Select the Test, and Start Test.

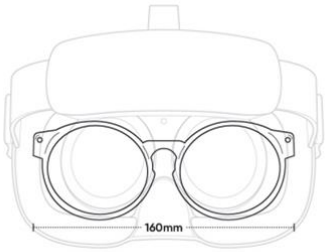


Figure 4: Prescription Glasses Fit

"If the patient vision needs correction, they can wear glasses up to 16 cm (6.3 inches) or insert the trial lens adaptors and put in the correct vision trial lens for the patient. Align the lens with the degree numbers for astigmatism. Make sure the letters and the fixation red light is in best focus. The visual field test will make measurements of the central and peripheral vision. It is very critical to fixate straight ahead, observing the red fixation light. There will be other stimuli lights around the vision that will flash on and off. No matter how dim or bright the light flashes are; if a flash of light is observed or perceived, press the hand trigger button with the thumb that is being held in the hand (see photo of trigger button in Figure 5*). If feeling fatigued, ask the operator to pause the test. This will pause the test for the purpose of taking a break and resting. To resume the test, ask the operator to resume the test and continue with responding to the flashing lights by pressing the handheld trigger button. The test will take anywhere from 2 to 10 minutes."*

Figure 5: Clicker

1.4 Electronic User Manual Access

The VF2000NEO Device User Manual is in Acrobat PDF format. It is included in the VF2000NEO Controller Tablet. The User guide is accessible by tapping on the VF2000NEO IFU Icon on the Controller Tablet.

1.5 Additional References

The User Manual cannot possibly cover every situation you may encounter with the VF2000NEO Device, especially interpretation questions. A book named "**Automated Static Perimetry"**, Second Edition, by Douglas R. Anderson and Vincent Michael Patella (Mosby, Inc., St. Louis), is recommended for an in-depth information and analysis of visual fields.

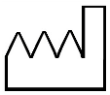
1.6 Symbols

 **Caution: consult accompanying documents.** Note: There are important operating and maintenance instructions found in the manual.

 **Presence of electrical shock hazard.** Note: Indicates risk of electrical shock due to the presence of un-insulated high voltage inside the instrument. Do not remove the instrument cover or part.


Type B Applied Parts


Manufacturer


Date of manufacture

Authorized European Community Representative

Serial Number

Model

Figure 6: Additional symbols appearing on the VF2000NEO Device

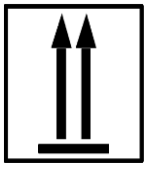
1.7 Protective Packing Symbols

The protective packing symbols on the shipping carton specify the handling requirements and the transport and storage conditions for the VF2000NEO Device as it is shipped from the factory. Note, these symbols are included if your VF2000NEO Device must be stored for a period of time, prior to its set up and use.

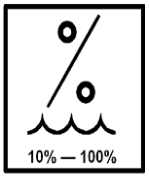
1.8 Handling Requirements


Fragile

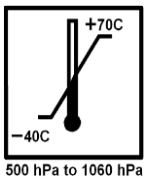

Keep dry


This end up

Transportation and Storage Conditions



Relative Humidity: 10% to 100%, including condensation



Temperature: -40 to +70 deg. C; Atmospheric Pressure: 500 hPa to 1060 hPa

1.9 Instrument Disposition

When it comes time to upgrade the VF2000NEO Device, please contact Micro Medical Devices Inc. to inquire about trade-in or upgrade values we may offer. Should you not wish to trade in the instrument, please see the Disposal section below.

1.10 Disposal

⚠

This product contains electronic components. At the end of its lifetime, the product should be disposed of in accordance with the relevant national regulations.

1.11 Disposal of the Product within the European Union (EU)

In accordance with applicable EU guidelines at the time at which the product was brought onto the market, the product specified on the consignment note is not to be disposed of via the domestic waste disposal system or communal waste disposal facilities.

For further information on disposal of this product, please contact your local dealer or the manufacturer or its legal successor company. Please read the latest internet information provided by the manufacturer.

Where the product or its components are resold, the seller must inform the buyer that the product must be disposed of in accordance with the currently applicable national regulations.

1.12 WARNING: User Changes to Software or Hardware

The VF2000NEO Device is a medical device. The software and hardware have been designed in accordance with U.S., European and other international medical device standards designed to protect clinicians, users and patients from potential harm caused by mechanical, diagnostic, or therapeutic failures. Unauthorized modification of VF2000NEO Device software or hardware (including peripherals) can jeopardize the safety of operators and patients, the performance of the instrument, and the integrity of patient data. It also voids the instrument warranty.

1.13 Approved Software

Use of software supplied or approved by Micro Medical Devices Inc. for the VF2000NEO Device is authorized. For the current list of approved software, call Micro Medical Devices Inc. Customer Care: In the U.S., call 818-222-3310. Outside the U.S., contact your local Micro Medical Devices Inc. distributor.

Note: Micro Medical Devices Inc. does not provide technical support for the use of unapproved third-party software.

1.14 Instrument Installation

Only an authorized Micro Medical Devices Inc. service representative should install the VF2000NEO Device. In consultation with the buyer, Micro Medical Devices Inc. schedules one free on-site or virtual installation appointment after instrument delivery. System installation and operator training require approximately one-half business day.

1.15 Care in Handling

Use extreme care when handling and transporting the VF2000NEO Device shipping boxes. The instrument contains fragile optics that have been precisely aligned at the factory.

1.16 Installation Requirements

The VF2000NEO Devices need not operate on a dedicated power outlet. But, for charging of the device, a dedicated power outlet is required. Based on your specification, your VF2000NEO Device can use either 100V, 115V or 230V line voltage.

1.17 Cleaning Instructions

The VF2000NEO Device’s VR Goggles can be cleaned using alcohol wipes or alcohol pads between patients. Avoid using organic solvents, to clean the device. When necessary, use disposable facemasks and hair-caps, which are worn by the patient prior to wearing the VR Goggle, to prevent the device from coming in direct contact with patients.

1.18 Tips to Avoid Damage

- Only Micro Medical Devices Inc. authorized technicians should disassemble or service this instrument. In the case of malfunction, error messages or operational problems, call Micro Medical Devices Inc. Customer Care: In the U.S., call 818-222-3310. Outside the U.S., contact your local Micro Medical Devices Inc. distributor.
- This instrument has no special measures to protect against harmful ingress of water or other liquids (classified IPXO—ordinary equipment). Do not place containers of liquid on or near the instrument, nor use aerosols on or near it.
- In case of emergency related to the instrument, unplug the charging power cord from the wall outlet and call for service immediately.
- There are no user-replaceable parts in the instrument. For the replacement of any component, accessory, or peripheral, except fuses or the keyboard, call Micro Medical Devices Inc. Customer Care: In the U.S., call 818-222-3310. Outside the U.S., contact your local Micro Medical Devices Inc. distributor.

- Although this instrument is designed for continuous operation, it should be turned off when not in use for an extended period.
- This instrument operates according to specifications under standard indoor office (fluorescent) lighting conditions.
- The headset should not be left out in the sunlight. Direct sunlight on the lenses will concentrate the light and cause heat damage to the screen and is a fire hazard.

Note: Users are not authorized to dismantle or modify the VF2000NEO Device hardware. To dismantle or modify the hardware, contact Micro Medical Devices Inc. service technician. Failure to do so voids all warranties offered with the VF2000NEO Device.

1.19 VF2000NEO Device Embedded License

Each VF2000NEO Device is issued with an embedded Android operating system license.

1.20 This instrument is classified as follows:

- Class I Equipment – Protection against electrical shock.
- Type B – Degree of protection against electric shock of applied part (eyes and cheeks, surrounding area of eye).
- Ordinary Equipment (IPX0)– Degree of protection against ingress of liquids (none).
- Continuous Operation – Mode of operation.

1.21 General Safety Requirements

- Although the VF2000NEO Device is designed for continuous operation, it should be turned off when not required for an extended period. The VF2000NEO Device should be used in a cool, dry dust-free setting.
- Always use the instrument cover to protect the VF2000NEO Device when it is not in use.
- Do NOT place the cover over the instrument when the VF2000NEO Device is turned on, as loss of proper airflow can cause overheating and damage to sensitive components.
- Do NOT place any objects on top of the instrument.
- Do NOT place any container holding liquid near the instrument.

1.22 Warnings

WARNING: Do NOT block the ventilation openings. These allow for the release of heat generated during operation. A buildup of heat due to ventilation opening blockage can cause failures which may result in a fire hazard.

WARNING: During Charging to prevent electric shock, the instrument must be plugged into an earthed ground outlet. Do not remove or disable the ground pin.

WARNING: Do not allow patient to stand up immediately after the test and allow for 2 minutes of recovery after the completion of the test.

1.23 About Visual Fields

One of the most essential tools in the modern ophthalmic office is the automated perimeter, used to evaluate the visual field.

The purpose of visual field testing, or perimetry, is to provide information critical to:

- diagnosing ocular diseases, especially glaucoma
- evaluating neurological diseases
- monitoring the progress of ocular and neurological diseases

Visual field testing can lead to early detection and treatment of sight related diseases. In the case of glaucoma, visual fields play a major role in identifying visual field defects and evaluating the efficacy of the therapy used to control the disease process.

1.24 What a Visual Field Test Measure

When evaluating visual performance, clinicians are primarily interested in two retinal functions: resolution and contrast sensitivity. Resolution is the ability to identify discrete forms (letters, numbers, symbols), and is commonly measured with the visual field tests. Resolution rapidly diminishes with increasing distance from the fovea and is, therefore, a poor indicator of overall visual performance.

A better means of evaluating visual function—especially those areas less sensitive than the fovea—is contrast sensitivity testing. Contrast sensitivity is the ability to detect a stimulus (spot of light or other target) against a darker or brighter background. VF2000NEO Device perimetry may be thought of as contrast sensitivity testing applied throughout the peripheral visual field.

In perimetry, the term “threshold” is used to describe a very specific level of stimulus detection. The threshold represents the point at which a stimulus is seen 50% of the time and missed 50% of the time. The assumption is that all stimuli brighter than the threshold value will be visualized, and all stimuli dimmer will be missed. Reviewing the threshold value at each point tested in the visual field is an important part of the diagnostic process.

Visual field tests can yield information that is general in nature, as with screening tests, or more exacting and quantitative, as with threshold tests. In deciding which test type is most appropriate for a patient, the practitioner is influenced by many factors, including the patient’s presenting complaint, family history, age, degree of cooperation, and time available to run the test.

1.25 Normal Versus Pathologic Fields

The visual field normally extends more than 90º temporally, 60º nasally and superiorly, and about 70º inferiorly. That means a person can potentially perceive stimuli within this range while staring at a fixed point.

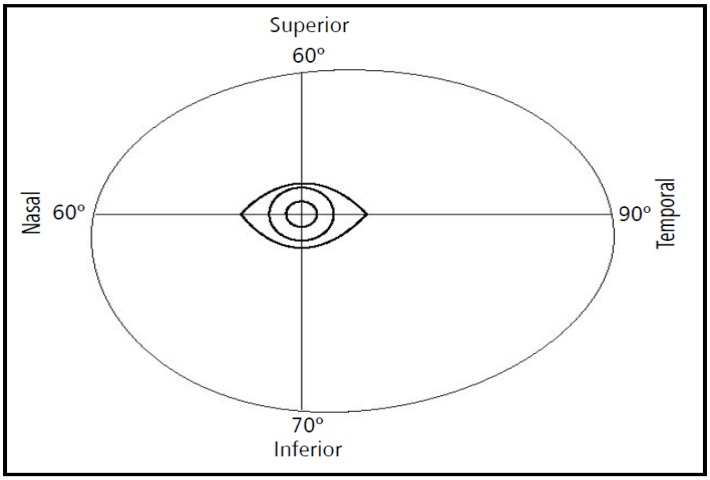


Figure 7: The Boundaries of Normal Visual Field

A more comprehensive understanding of the normal field considers that visual sensitivity is not constant (or equal) throughout the range. As previously stated, vision is most acute at the fovea and decreases toward the periphery of the retina. It is easy to see why the visual field is often expressed as a “hill of vision in a sea of darkness”.

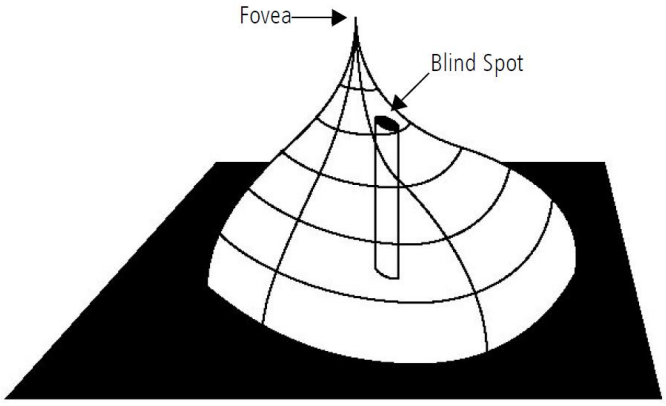


Figure 8: The Normal Hill of Vision

Several factors affect the normal hill of vision, causing variations in its overall height and shape. Among them are a patient’s age, ambient light, stimulus size, and stimulus duration. In general, deviations from the normal hill of vision are viewed as visual field defects and caused by some pathological change.

A visual field defect, or scotoma, is categorized as either relative or absolute. A relative defect is an area that has depressed vision or less than normal sensitivity; an absolute defect is an area where the perception of light is absent. The point at which the optic nerve enters the retina is referred to as the blind spot and is an example of an absolute scotoma.

Some defect patterns are characteristic of certain diseases, a fact which makes visual field testing a valuable part of the diagnostic process. Furthermore, by having patients repeat the same tests at later dates, practitioners gain insight into the progression of the disease and the effectiveness of treatment.

1.26 Methods of Testing the Visual Field

Over the years, visual field-testing devices have varied in size, complexity, and testing methodology. The fundamental premise has remained the same, however; patients must respond when they see a stimulus.

Static threshold testing evaluates retinal function. The term “static” refers to a stationary stimulus being used. In static testing, predefined test locations in the visual field are probed. Through a series of stimulus presentations of varying brightness intensities, the threshold value is determined for each test point. When evaluating static test results, clinicians are looking at the topography or contour of the hill of vision, and whether depressions are evident.

In a second type of retinal evaluation, called kinetic testing, a light stimulus of fixed characteristics is moved into the visual field from a non-seeing area, until it is detected by the patient. Typically, the stimulus is brought toward the center from several directions and the operator marks the location at which the patient first detects the stimulus (threshold point).

1.27 Patient Fixation and Test Reliability

For any visual field test to be useful clinically, it must yield reliable results. One important factor affecting reliability is the steadiness of patient fixation. Unless the eye being tested fixates accurately on the target while responding to stimuli, the results are unreliable.

Other factors adversely affecting reliability are:

- patient fatigue and anxiety
- poor test instructions
- patient discomfort
- improper near vision correction for central testing

1.28 Benefits of Computerized Perimetry

Certainly, the advancements in microprocessor technology within the last 20 years have had a profound effect on perimetry. Perimeters have evolved into a more precise measuring tool yielding highly repeatable results.

These changes are better appreciated by examining the benefits computerized perimeters bring to both patient and professional:

- Reproducible testing conditions
- Data storage capability: results can be compared over time and analyzed using expert-system software
- More sensitive testing: advances in algorithm development has made static perimetry superior to the kinetic method for identifying defects
- Ease of operation; menu-driven software makes automated perimeters easy to learn and use

1.29 The VF2000NEO Device Advantage

Micro Medical Devices Inc. took on the challenge of improving the testing experience for the patient, the operator, and the practitioner.

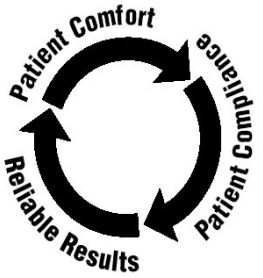


Figure 9: Priority Cycle for Medical Devices

1.30 Ergonomic Design

The VF Device relieves many physical discomforts associated with visual field testing. The lack of chin rest and bowl shape allow patients to assume a more natural and relaxed sitting position when taking tests. The VF2000NEO Device improves patient comfort by permitting the VF2000NEO Device to adjust to the patient instead of the patient adjusting to the instrument. This especially is important for wheelchair bound patients.

The patient response button is easy to operate, especially for patients who have limited use of their hands, for instance, patients with arthritis. The uniquely shaped wireless button on the clicker that fits the contour of the hand is meant for better comfort. The hand trigger response button transmits results to the controller as it is pressed to give immediate feedback to the operator.

1.31 Easy Operation

Sophisticated instrumentation need not be complicated. The VF2000NEO Device offers several features intended to make the instrument easier to use:

- Touch screen design in the controller speeds data input.
- Menu and icon commands simplify operation using the controller.
- Virtual reality helps in reducing costs for equipment set-up, eliminates the need of office space and eliminates the requirement of maintaining conditions such as appropriate distance between screen and patient, lighting conditions etc.
- In-built video training and practice tests available before patient starts the test.
- Offering 2 modes of operation: online and offline whereby the test can be conducted in both the modes and the reports are saved in the master database in both modes.
- Sync option that allows switching from offline to online mode; once internet access is available data is sent from master database to local database using the sync option.
- Allows change of IP address when user moves from one office to another or one location to another.
- Volume for voices generated by the VR goggle can be easily controlled using the controller.

1.32 Intended Use

The Micro Medical Devices Inc. VF2000NEO (Visual Field) Device is a virtual reality-based perimeter which is intended to be used to measure the visual field of the eye.

1.33 Indications for Use

The Micro Medical Devices Inc. VF2000NEO device is a virtual reality-based perimeter intended to identify visual field defects for the purposes of screening, monitoring, and assisting in the diagnosis and management of ocular diseases such as glaucoma, and related neurological disorders.

The "*Visual Field*" is a software module for the Micro Medical Devices Inc. VF2000NEO provided in the VR goggles, for the availability of all required tests with appropriate lighting and color to the patient within the virtual reality environment; also ensures utmost convenience with a training consisting of picture instructions within.

The "*Visual Field* is a software module for the Micro Medical Devices Inc. VF2000NEO provided in the controller device that assists practitioners with the entry of patient information; manage the selection of type and sub-type the test; view and manage progression of test; generate test reports.

NOTE: The perimetry results provided by the Micro Medical Devices Inc. VF2000NEO Device are an aid to interpretation, not a diagnosis. The doctor's judgment is still the most important element in determining the clinical significance of the results, including considering the limitations of the statistical package.

Charging your device: Controller & Test Device must be charged using the cables provided. The Clicker works on AAA batteries.

1.34 Patient Population

The Micro Medical Devices Inc. VF2000NEO may be used on all adults and children over the age of six in need of diagnostic evaluation of the eye. This includes (but is not limited to) patients with the following disabilities or challenges:

- Wheelchair user
- Very low or unmeasurable Visual Fields
- Postural problems
- Fixation problems
- Deafness
- Large body
- There is no general requirement that the patient be able to sit upright as there is no need to place their face in the chin and forehead rest of the instrument. In fact, the instrument itself is wearable over the eyes.

1.35 Part of the Body

The Micro Medical Devices Inc. VF2000NEO physically interacts with the patient's eye and surrounding area below the eye. The patient's hand and fingers (or similar ability) are also required to press the Patient Response button on the remote-control clicker.

1.36 Application

The Micro Medical Devices Inc. VF2000NEO is designed for continuous use, although it is expected that most sites operate the instrument for 10 hours or less per day, indoors, within a medical office or hospital setting. There are no specific Operating Environment specifications (clean air free of soot, vapors from adhesives, grease, or volatile organic chemicals). Application related warnings are given in Chapter (1), "Introduction & Instrument Setup," and elsewhere.

1.37 User Profile

It is assumed the user to be clinicians and end user to be the patient.

Users can be the one with professional training or experience in the use of ophthalmic equipment, and in diagnostic interpretation of the test results, such as follows:

- Ophthalmologist
- Optometrist
- Nurse
- Certified Medical Technician
- Ophthalmic Photographer
- Non-certified Assistant

A complete training module is in-built within the VF2000NEO device for all types of users. Also, this manual contains information that will aid in the proper instrument operation and interpretation of the resultant data.

However, specific assumptions regarding the profiles of individuals performing instrument operation or data interpretation are given below:

1.38 Instrument Operation

The instrument setup is composed of three parts.

A. Office administrator Setup procedure. Refer to Chapter 4 Section 0
B. Controller setup procedure. Refer to Chapter 5 Section 0 & 1.
C. Visor operational procedure. Refer to Section 1.3

The Instrument Controller is operated under the supervision of the Doctor, Nurse, or Technician to setup the instrument and properly enter the patient information.

The Visor Instrument operation by the end-user (patient) is limited to taking the test through gaze input and pressing the Patient Response button whenever required.

The user should be able to perform all the following tasks:

- Power on the instrument
- Enter, find, and modify patient identifying data
- Clean surfaces that contact patient
- Select and initiate a test
- Review and save a test or try again
- Generate an analysis report

- Review the analysis report for completeness
- Save, print, or export an analysis report
- Archive data
- Power off the instrument
- Charge the instrument after every use, ensure battery levels are adequate for each test.

1.39 Data Interpretation

Demographic:

The user should be one of the following:

- Ophthalmologist or other Medical Doctors
- Optometrist or equivalent

Occupational Skills:

The user should have the following skills:

- See Section 1.37: User Profile
- Ability to work with elderly patients and those with disabilities Demographic Occupational Skills

1.40 Job Requirements

The user should have training and certification in the analysis and treatment of ophthalmic diseases or other eye-related medical issues as required by governing bodies.

1.41 Purpose of This User Manual

Micro Medical Devices Inc. designed this User Manual to serve as a training, usage, and reference guide. While we offer training in the use of the VF2000NEO device, we do not offer instruction in diagnostic interpretation. Hence, this manual does not attempt to do so.

To fully appreciate the capabilities of the VF2000NEO device and to develop good testing techniques, we recommend that you rely on this User Manual as your training and reference guide. It has been designed to make learning easy. The concise step-by-step instructions and accompanying illustrations help you get started quickly and with more confidence.

We think you will enjoy working with the VF2000NEO device. The friendly VR technology makes it simple to learn and easy to operate. For optimum results:

- Read your User Manual in the order written.
- Read it before using the instrument.
- Practice using the VF2000NEO device by first testing staff members, before using it with patients.

This User Guide along with VF2000NEO Training guides are provided on the Controller as well. To access the User Guide and the training videos:

a) Exit the VF2000NEO app on the controller.
b) On the Home-screen, find a folder called “VF2000NEO Training”

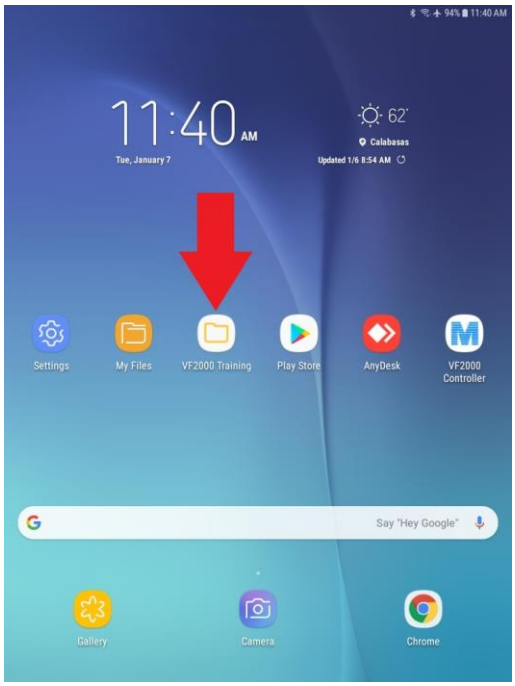


Figure 10: VF2000NEO Training folder on the Controller Home Screen

1.42 Text Conventions

The terms “select”, “choose”, “touch” and “press” are used interchangeably. Each term means to initiate an operator action using the touch screen on the controller or use the patient response button on the remote control or on the side of the VR goggle. The terms “internal storage” and “external storage” are used to reference the data storage device standard on the VF2000NEO device model.

UPPER CASE LETTERS are reserved for references to specific command buttons found on the touch screen. The exceptions to this are messages on test printouts.

Italicized words are used to identify the icon buttons on the right border of the screen, the titles of figures, pictures, tables, and special notes in this manual.

Bold words are used to highlight warnings and section headings.

Chains of menu items are indicated with the use of the “>” symbol between items. For example, “File>Exit” directs you to select Exit in the File menu.

2. What is in the Package?

2.1 System Components

VF2000 Pico NEO Headset

Android 8” Tablet Controller Device

2 Bluetooth Clickers

Tablet USB Charger

User Guide

Carrying Case

Microfiber Cloth

Trial Lens Adaptors

Facemasks

Quick Start Guide

FAQ

Credential Sheet

Step-by-Step Guide

Contents of the box as appears in **Figure 11** are:

Figure 11: Device Box on Opening

a) **Test Device:** The test device comprises of a virtual reality headset and is a head-mounted device. It comprises of a stereoscopic head mounted display to view virtual reality applications on the internal 4K screen. The device is the best on the market for screen resolution.

Figure 12: VR Headset

b) **Clicker:** A small hand-held device with buttons used to receive inputs from the patient during the test on the Test Device. The clicker is automatically connected to the Test Device upon first use. If it is not linked to the Test Device, follow the steps in Chapter 3 Section 4.

Figure 13: Clicker

c) **Controller Tablet:** A tablet device which is part of the VF2000NEO system enables the clinician to access the Controller application for the scans/tests.
d) **Chargers (x2):** A micro-USB cord for the tablet & a USB-C cord for the headset.
e) **Microfiber Cloth:** A cloth for wiping the lenses and screens.

f) **Face Mask:** A pack of sterile cotton face mask is included in the box. A new one is worn by each patient before putting on the VR goggles for the test.

Figure 14: Wired USB C-type Charger and Face Mask

2.2 Cloud Storage

Every unit comes with 2 years of free web-based cloud storage that is accessible from portal.micromedinc.com. The cloud storage provides a secure way to transfer reports/data from different devices to a computer with an EMR/EHR on it. It is not necessary for the use of the device.

3. Basic Operation

3.1 Charging your device

The test device needs to be charged before use. A fast charger with a C type wire is used to charge the VR goggles.

To verify that the device is charging, a lightning bolt appears on the battery icon on the top center of the home screen. We recommend that throughout the day and in between patients, the device be charged using the C type USB cable.

Figure 15: Charging the test device

3.2 Turning on the Devices

To turn on the VR Headset, press the power button on the bottom of the headset. After powering on the VR headset, you can turn on the clicker by pressing the Pico Symbol. The clicker will start flashing blue to indicate it is looking for the headset and turn off when it has connected. If you need to move the menu to in front of yourself, press and hold the Pico symbol while pointing the clicker in the direction you want to move the menu too. When the controller is on, click the VF2000NEO Controller app to launch the application. The VF2000NEO app needs to be open on the Test Device after turning it on.

Figure 16: Power Buttons for Controller, Test Device and Clicker

3.3 Connecting to Wi-Fi

As soon as the devices are charged and ready to take scans, the VR Headset needs to be connected to an available Wi-Fi connection. From the main menu screen, select the Wi-Fis icon at the top of the center screen. Select Network and select your network from the list of available Wi-fi. Enter the password in using the keyboard shown at the bottom of the screen and tap enter.

The same process is followed on the Controller- Settings on the controller is selected from the home screen and the correct Wi-Fi network is selected. Good Wi-Fi connection is necessary for the tests to be done. The devices can even be connected using a Mobile Hotspot on an external cellular network device (a cell phone with active Hotspot option) which can be used as a router. The process to connect to the cell phone Hotspot is like connecting to a Wi-Fi router.

3.4 Connecting Clicker to Test Device

The clicker is paired to the Test Device using Bluetooth before shipping. In case this connection is not found, following are the steps to connect the clicker to the Test Device:

- Go to “settings” ==> “Controller”, click on “add controller”.
- Press and hold the HOME button and the TRIGGER button of the Controller at the same time until the red and blue lights of the Controller flashing alternately.
- Then follow the instructions on the VR Headset screen.

If the clicker is still not connecting:

- Ensure that the batteries do not need to be replaced. If battery level is low, then charge the controller.
- Power on VR headset.
- From the home screen, go to the controller icon, located at the top of the screen.
- Go to “Controller” –> “Add Controller”.
- Follow the prompts to reset the hand controller to the VR headset.

3.5 Modes of Operation

The device can be operated in 2 modes: Online and Offline.

Online: In online mode, The Controller is connected to the cloud and all changes get backed up on the server. This connection can be through Wi-Fi or Cellular Mobile Hotspot network. A copy of the report is also saved in the local files.

Offline: Offline mode is when the controller is not connected with the webserver network. Scans can still be performed but the data is stored locally on the controller. When the controller goes online, the data is saved to the network as well.

The Device does not need to be put in Online mode if the medical practice does not want to use our Cloud based storage and computing. The unit can be used exclusively in Offline mode.

3.6 Controller to Test Device Connection

There are 2 options

1. Wi-Fi Router - The Test Device and the Controller are connected using Wi-Fi. A feature available only for the Web Server controller.
2. Bluetooth – A feature available only on android devices, to connect with the Test Device using Bluetooth.

Following are the different modes of the device and instructions for use:

a) Figure 17 depicts when the controller is in online mode using Wi-Fi or Cellular network and the connection with the test device is made via Bluetooth. This mode is only available when the controller is an android device.

Figure 17: Depicts Online Mode

The Test Device is connected to the Controller using Wi-Fi/Hotspot, only in case of using Web Server.

⚠ WARNING: In a place where there is no internet connection (Wi-Fi or Mobile Hotspot), change the controller settings to ‘Offline mode’ on the controller.

3.7 Fixing the VR headset on the patient’s head

The test device is placed on patient’s head as shown in **Figure 3**. The straps are tightened to ensure a snug fit. This is done so that the test device does not move from the patient’s face during the test. The goggles are fastened tightly on the eye, to prevent the leakage of light from the side. Ideally, the test should be taken in a semi-dark room. Trial lens adaptors are provided if their vision needs correction.

3.8 Using the Eye Tracking

Before using the eye-tracking function, user calibration is required to obtain basic eyeball position information. It will automatically start before every test patient.

Ensure that the patient is wearing the headset correctly. Follow the instruction until the calibration is successful as seen below in Figure 18: Eye Tracking Calibration.

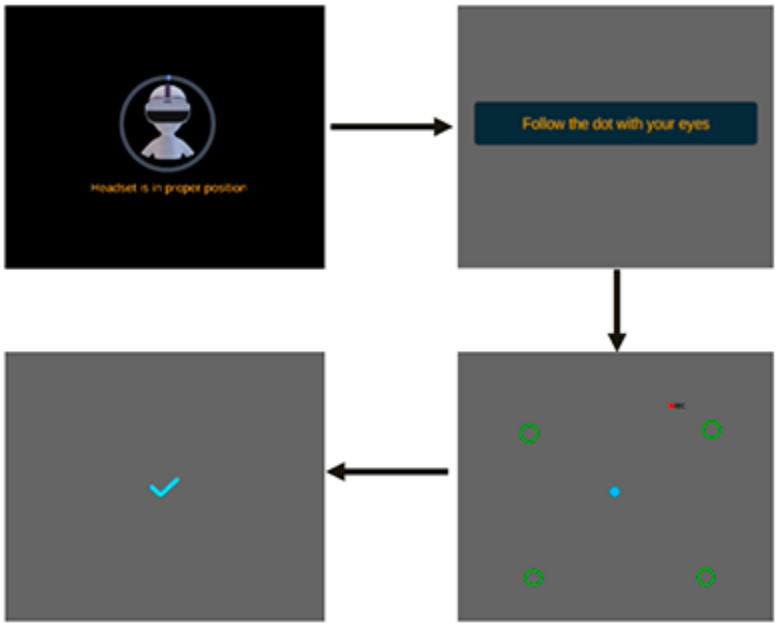


Figure 18: Eye Tracking Calibration

4. Web Portal

4.1 Office Administrator Setup Procedure

Micro Medical Devices Inc. sets up an office administrator when a system is purchased. The office administrator will receive log-in credentials and can set up their own password. The process is shown below. First go to www.portal.micromedinc.com and use the pre setup and mailed "Username" and "Password" to Login to your Admin Account.

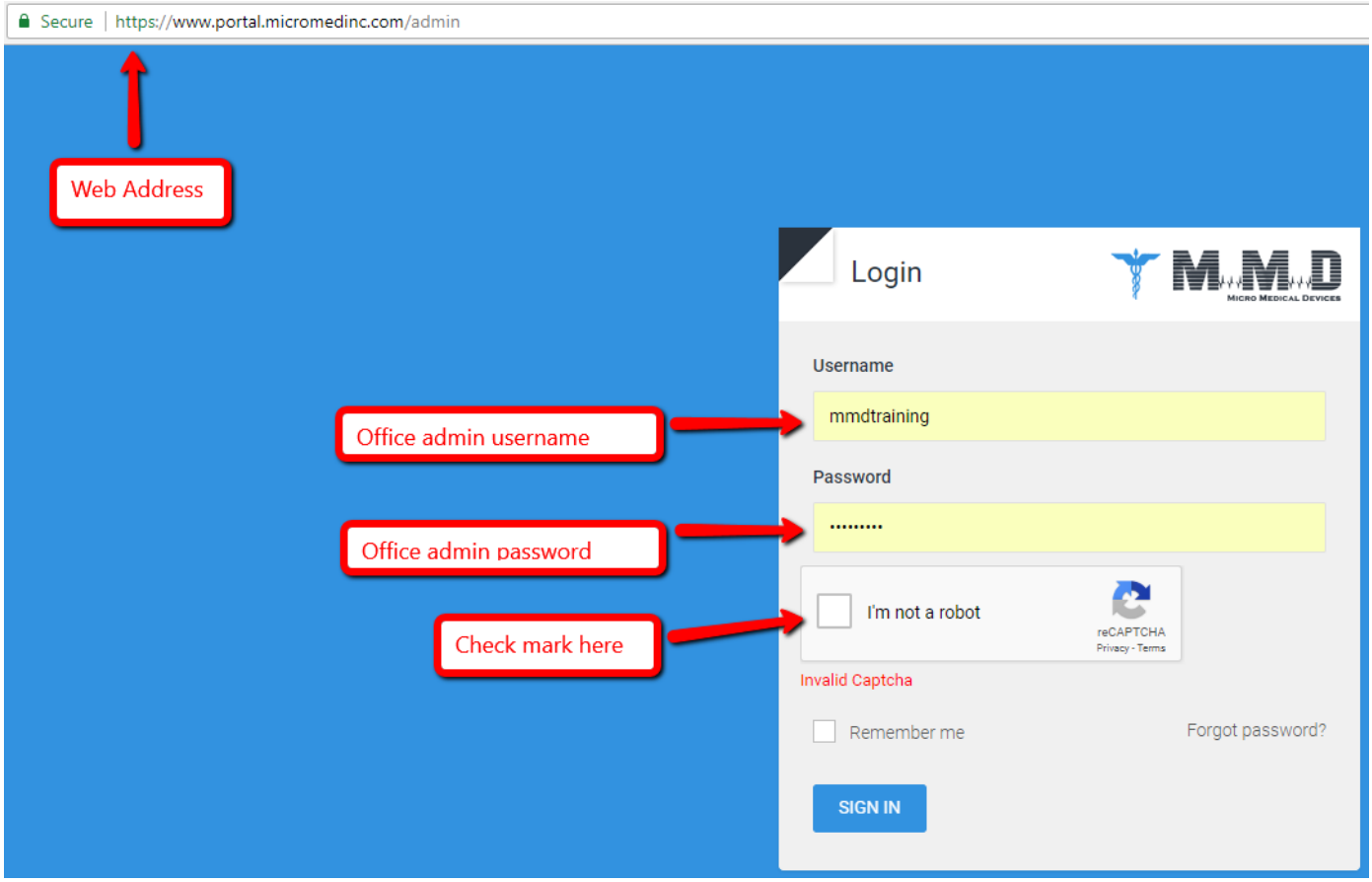


Figure 19: Office Admin Log-In

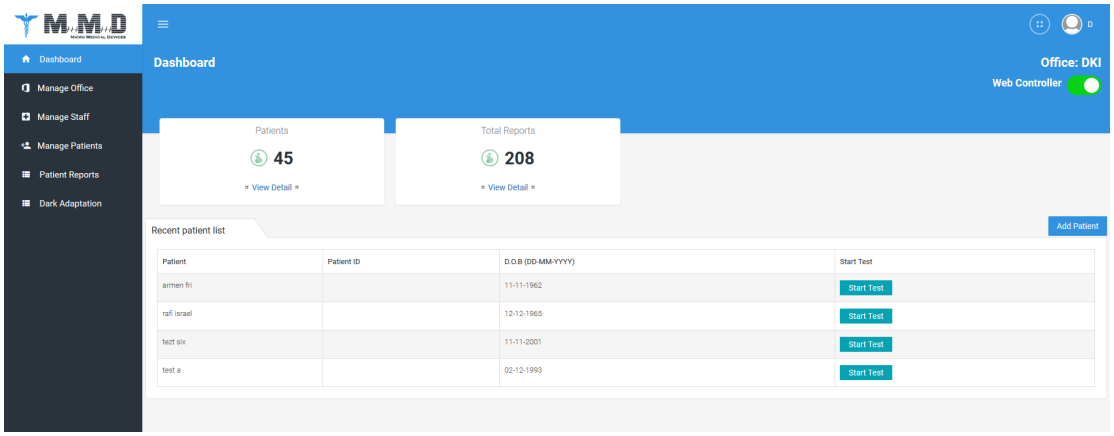


Figure 20: Office Admin Dashboard

After signing in as an Admin, the Office Administrator has access to the Dashboard as shown in **Figure 18: Office Admin Log-In**. The office Administrator Dashboard is shown after login-in. The options are to add staff members, Manage reports, Open different test reports, etc. Select "Manage Staff" from the list on the left and click on the "**Add Staff**" to add Staff member. Enter the name and password as shown in **Figure 22: Enter Staff Name and Setup,** Error! Reference source not found.**, Figure 23: Shows Staff**.

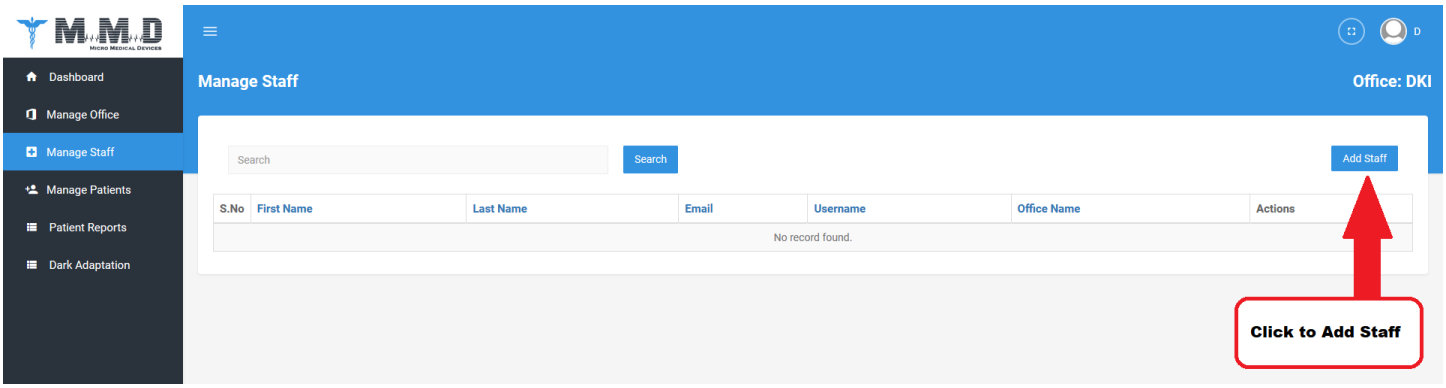


Figure 21: Add staff

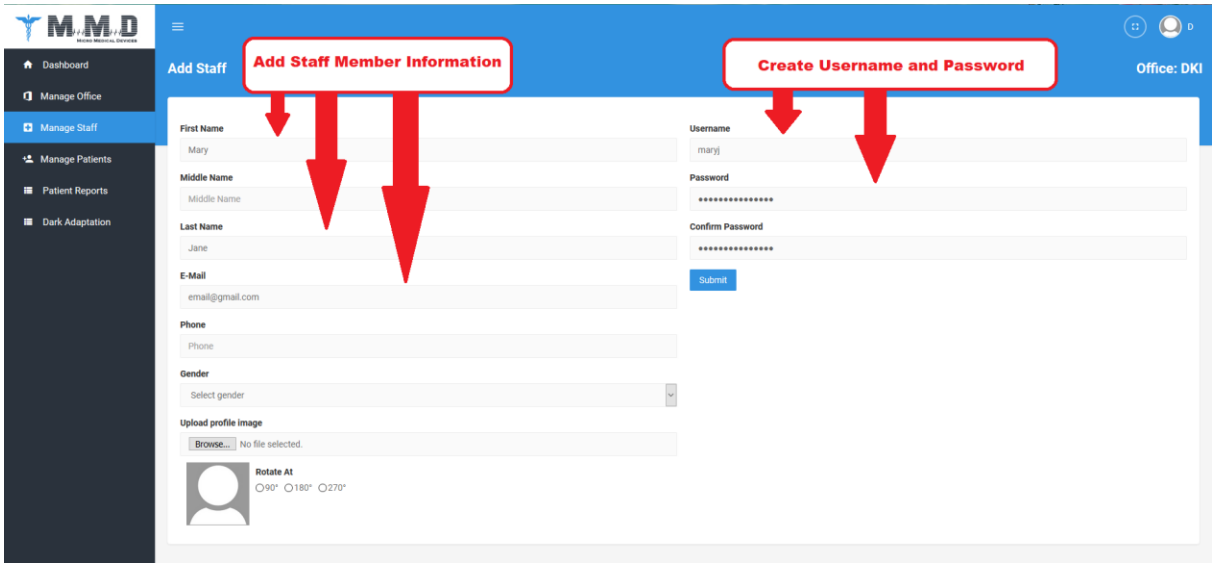


Figure 22: Enter Staff Name and Setup

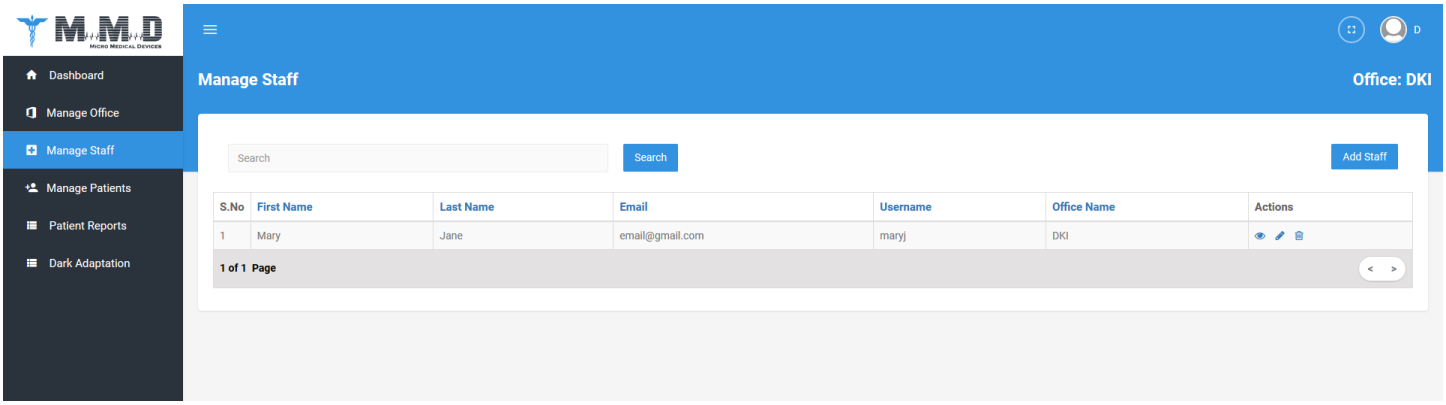


Figure 23: Shows Staff Information

Once Staff member names are added onto the system, the 'Manage Staff' page is displayed as in **Figure 23: Shows Staff.** From here, office admin can either view the staff member's details, edit the details or delete a staff member (indicated by the icon of an eye( ), a pencil ( ) and a recycle bin ( ).

4.2 Staff Log-In Procedure

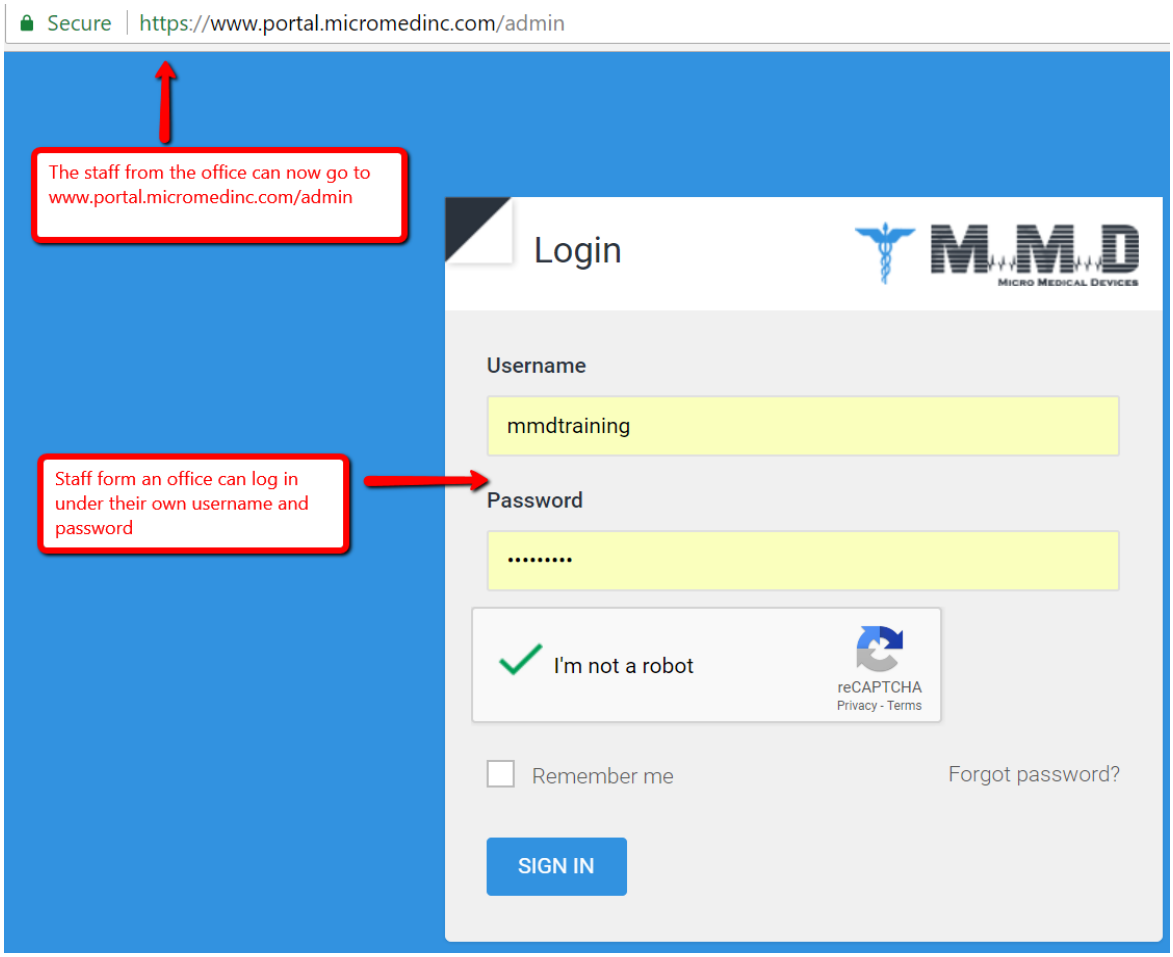


Figure 24: Office Staff Login Page

Office Staff can log in to the website www.portal.micromedinc.com and enter their Office Administrator assigned **Username** and **Password** to log in to their assigned Visual field Test Records as shown in Figure 24**.**

Once you are logged into the Staff account. You will be directed to the "**Dashboard**" page where you will see your recently added Patients. See Figure 25.

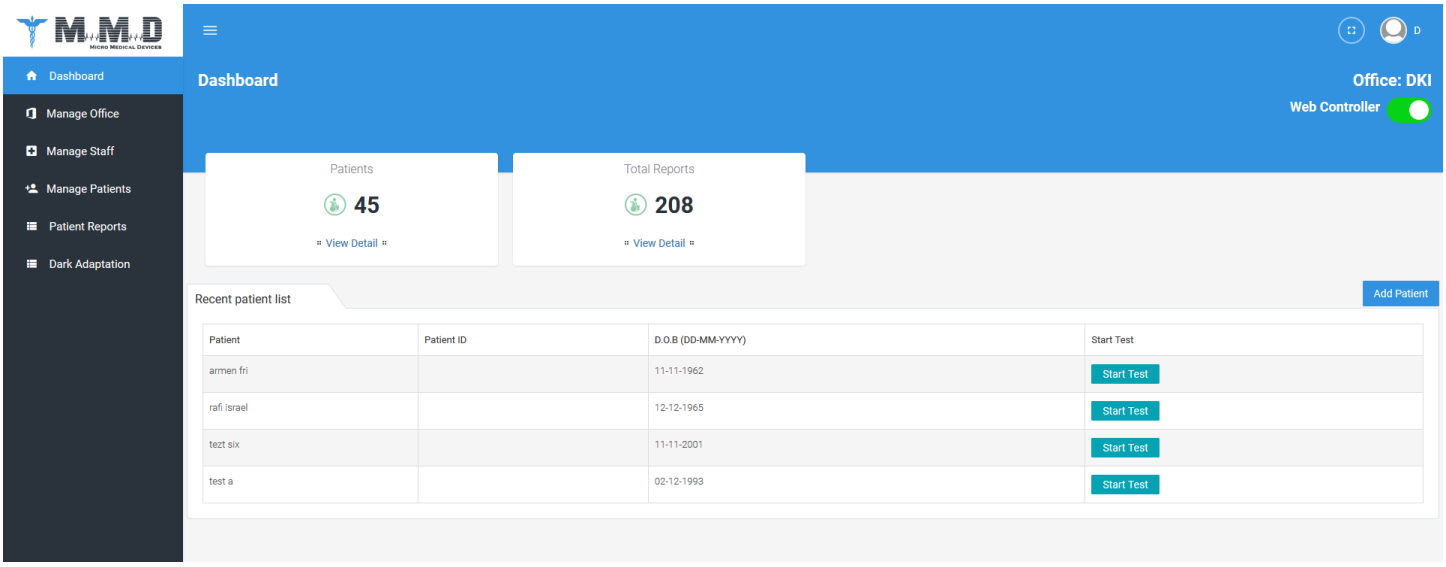


Figure 25: Office Start Dashboard

Above, is an example of a staff member logged in to the ABC office screen where they can see and manage office staff allocated patients and look at test reports. Note: The Office staff can only manage patients that are added by themselves or assigned by the Office Administrator. Now that office staff has a way of managing patient records from the website, go to section 4.4 to understand the controller operations menu options.

4.3 Adding a Patient

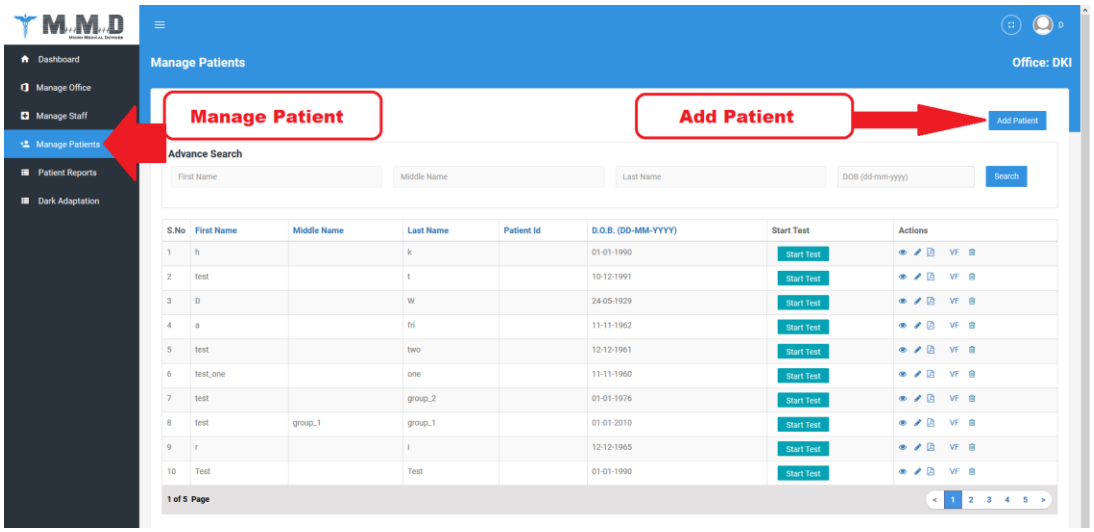


Figure 26: The Office Admin has an option to Manage Patients

The Office Admin has an option to Add Patients as shown above and manage them**.** Managing patients entails adding, editing, deleting, and archiving patient records.

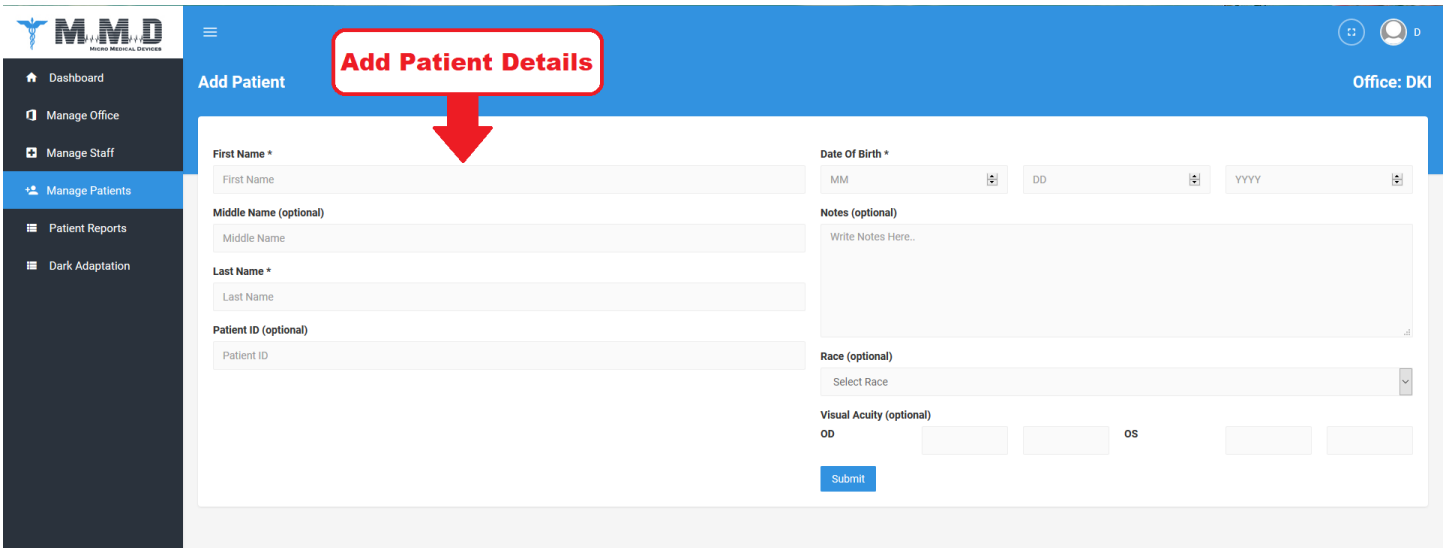


Figure 27: The Office Admin has the option to add patients

The necessary information to fill out is First Name, Last Name and Date of Birth. The date of birth is used in our proprietary Interactive Fast Threshold to speed up the Threshold test based upon a clinical study.

You can add a patient using the web server and it will appear on the Tablet Controller. After adding the patient on the web server, be sure to tap the sync button (as seen in Figure 33) on the tablet controller to bring the patient record in.

4.4 Using the Web Server Controller

Go to a web browser and open a new window. Log into the portal.micromedinc.com using the credentials that come with the device in a manilla envelope.

a) On the right side, click the “Manage Patients”. If the patient is not already added into the system, click “add patient” and fill out the required information (First name, Last name, DOB). Once the patient is in the system, click the “Start Test” button listed under the “Start Test” Column as shown in Figure 28: Click to Start Test.

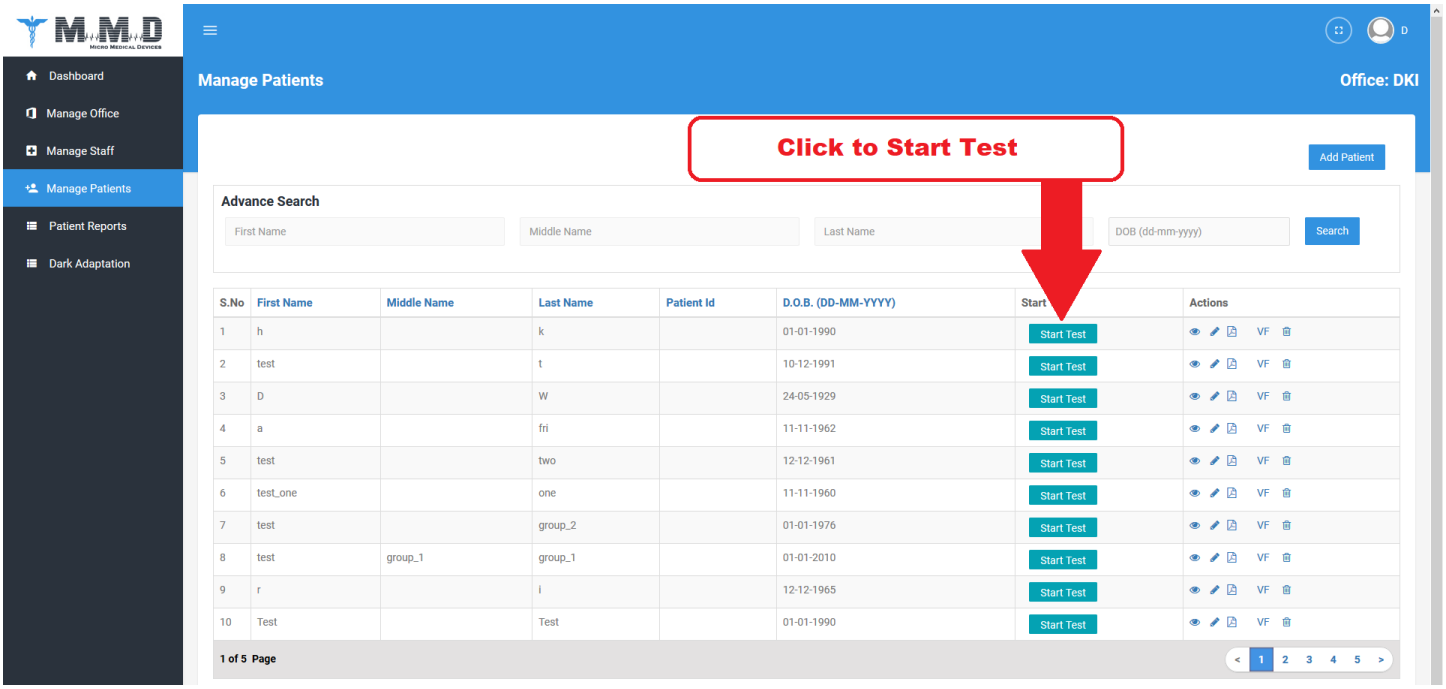


Figure 28: Click to Start Test

b) Launch the VF2000NEO App on the test device. Make sure the test device is connected to the internet.

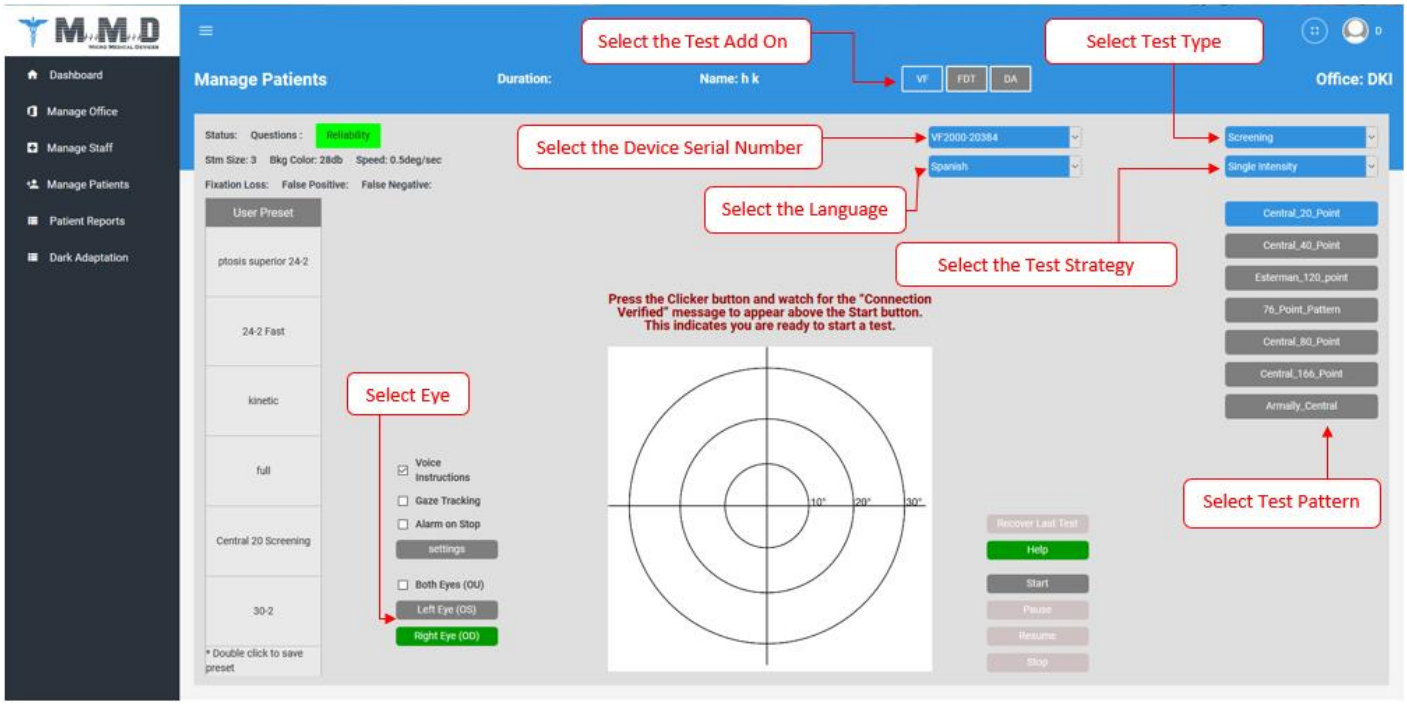


Figure 29: Web Server Test Page

c) After clicking “Start Test” you will be taken to the Test page. Make sure you have selected the right form of test if you have bought additional add-ons. Make sure you select the correct device under the list of devices. Select the Language for the voice instructions. Select the test and eye as well as any

of the check boxes. Refer to Figure 29: Web Server Test Page for the location of these options and messages.

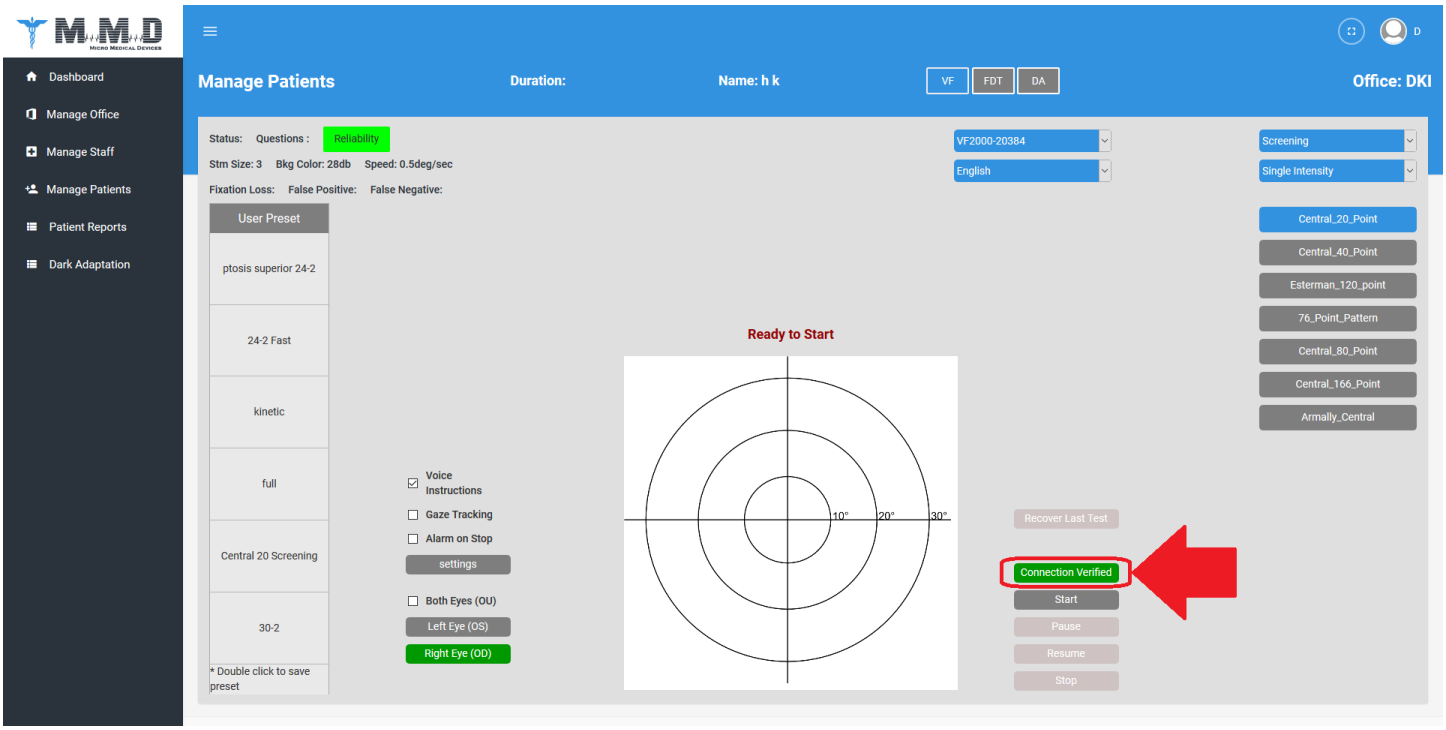


Figure 30: Web Server Connection Verified Message

d) Press the clicker once and make sure you see the “Full Connection Verified” Message appear. When ready, click start. On the Test device, you must click once for the device to fetch the test. The test should begin and prompted to click to start the test.

e) Once the test has finished, it will create a pop up of the report in a new tab. There will also be a button saying “View Report” that appears.

4.5 Downloading generated pdf reports

To view the visual field reports that are generated after conducting the test, Select “**Visual Field Report**” from the “**Dashboard**”. A list of all the reports generated will appear on the screen that are saved on your controller device. The desired report can be viewed and downloaded further as a pdf on a local drive of your computer as shown in Figure 31. To download the report directly to your EMR, you can login to the computer that has the EMR and further have the report directly downloaded in the inputs folder for your EMR.

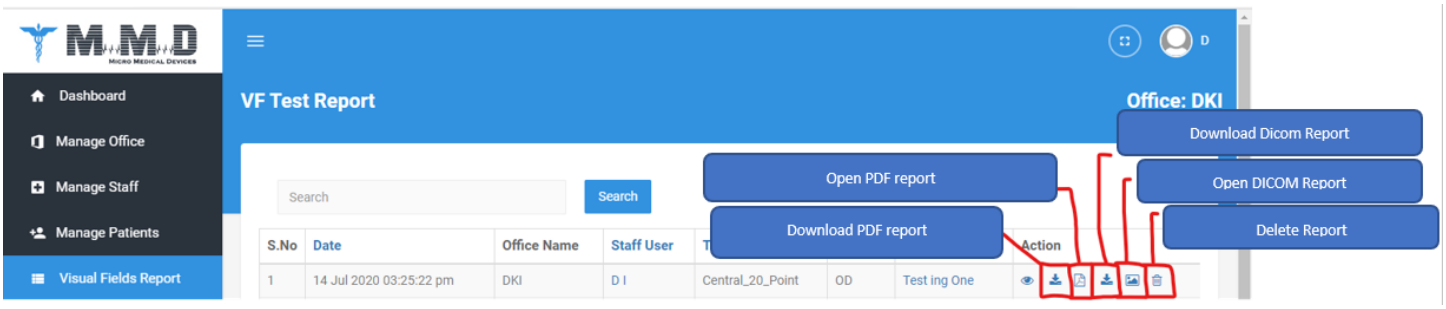


Figure 31: Visual Field Reports Page

5. Tablet Controller

5.1 Controller operations Menu Options

- The Controller is an Android Tablet device.
- Connect the Controller to your office wireless network or to a smart phone that has been setup for Personal Hotspot. Note: The "*VF2000NEO Test device"* must be connected to the network to update.
- To access the options offered through each menu, click on the menu headings. Then click on an option to select it. Click outside all menu options to make the options disappear.
- Some menus are fields tagged with a down-arrow (drop-down lists). To access these menu options, click on the down-arrow.
- Grayed-out menu options or buttons are not available.
- Here are the details of the Menu options available on the Controller.
- Launch the App named "VF2000NEO" on an Android Controller Tablet.

5.2 Controller Account login

After making sure the Controller is connected to the Wi-Fi (local network), the Office Staff can use their username and password that has been assigned by the office Administrator on the *"Login"* page as shown below.

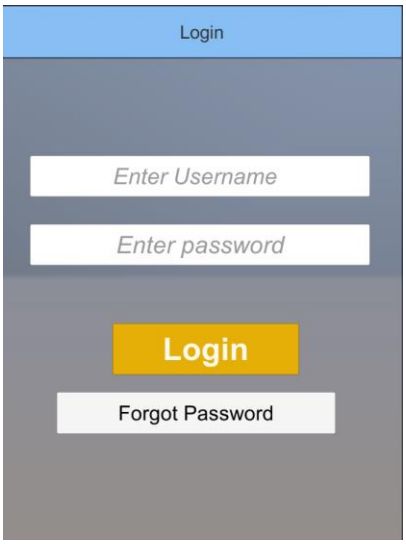


Figure 32: Controller Log in page

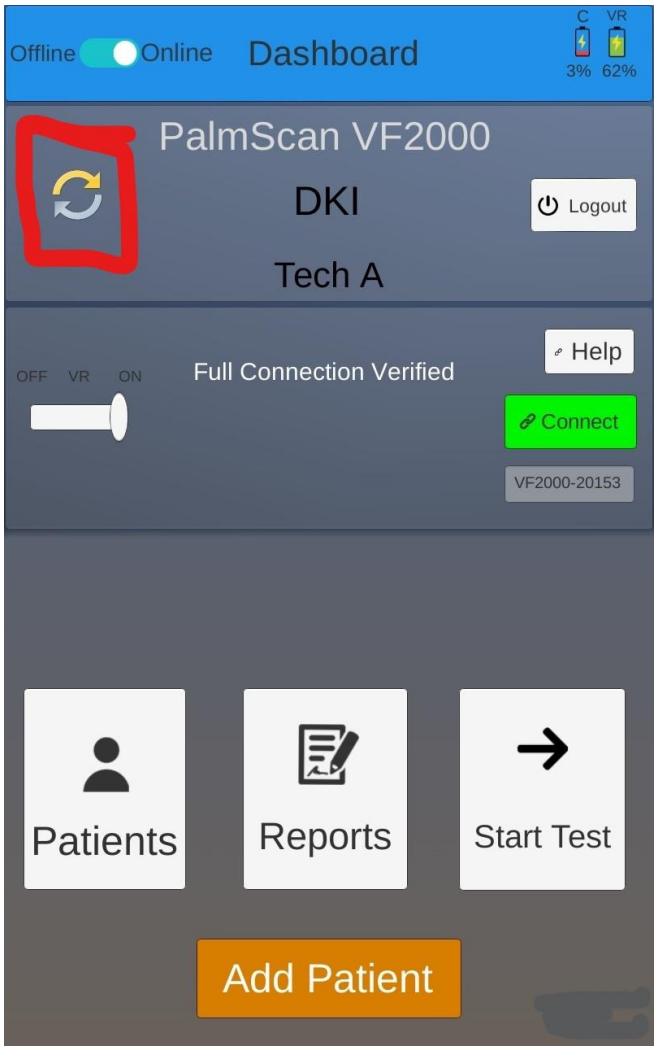


Figure 33: Select sync button to synchronize database from Webserver

After logging in, the controller should automatically update all the database information once the "**Sync icon"**  is selected. Sync is automatic after login.

5.3 Connecting to Test Device

This is the only mode of connection between the Tablet controller and the Test device.

Upon launching the VF2000NEO Controller app on the Tablet, the VF2000NEO app on the Test Device should be launched. Since the Test device is factory paired to the tablet controller, the "Connect**" button should be illuminated in green. This indicates that the Tablet controller is connected to the Test Device in Bluetooth Mode and no further action is needed to connect the Test device to the Tablet controller. If the "**Connect**" button is still grey, then follow the steps below.*
Note: The tablet screen when its ready to connect with the test device

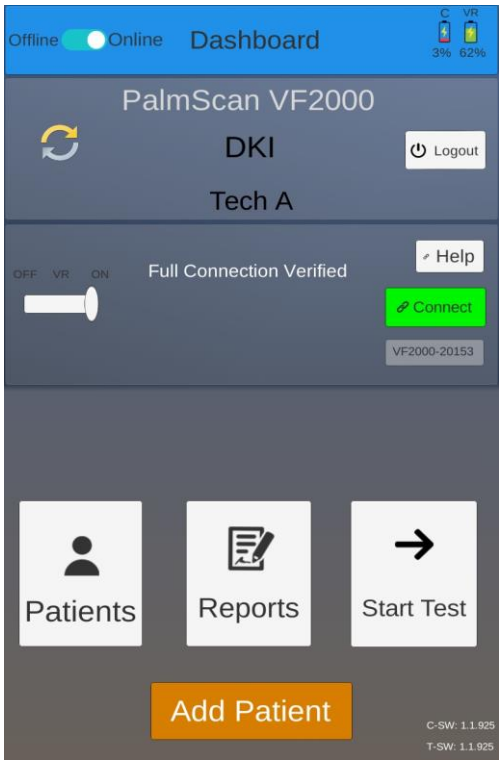


Figure 34: Controller screen: Ready to Connect with the Test Device

If a connection is not automatically made between the Tablet controller and the Test device, follow these steps to connect the test device to the controller using Bluetooth:

a) Open the VF2000NEO app on the Controller. Make sure the Test Device is turned on and the VF2000NEO app is launched.

b) Press the white "Connect" button on the Dashboard. It will flash red as it searches for the Test Device.

c) Upon connecting, the "Connect" button will remain solid green. If it turns back to white, proceed to step d.

⚠ WARNING: To prevent loss of connection between the Test Device and the controller, keep both devices within 30 feet of each other.

d) After following the pairing configuration above between the Test and Controller Devices, and successful connection confirmation is not established, follow the steps below in order:

   a. Exit the VF2000NEO application on both devices. Tap on the image of the two windows that appear on the controller/test device to the left of the home button below the screen or the square in the bottom right depending on your android controller tablet. Then press "Close All" or the trash can that appears at the bottom of the screen.

   b. Launch the VF2000NEO application on the Test Device.

   c. Launch the VF2000NEO application on the Controller Device.

d. Wait a few seconds and make sure the "**Connect**" button on the Controller Device turns green.

e. The Testing can proceed after following the procedure above.

Note: Once Bluetooth Pairing has been configured, the simple order of procedures mentioned in steps a to d above can be followed in all times for initiation of tests.

f) If the devices still do not pair after the above-mentioned steps, turn off the Bluetooth on the tablet and test device for a few seconds, then turn it back on. Proceed to redo step d after. If that does not solve the connection issue, try to restart the device. If that does not work, please contact us for more troubleshooting.

5.4 Data recovery

If the connection between the controller and the test device fails during the test, the test data is not lost and can be recovered. If the connection was established using Wi-Fi mode, the test device continues the test and sends all the data collected to the controller. If the connection was made via Bluetooth and you are not able to re-establish the connection, the following steps needs to be followed:

a) Exit the application on the test device and the Controller
b) Relaunch the VF2000NEO application on the test device
c) Relaunch the VF2000NEO application on the Controller
d) Reconnect the test device and the controller
e) On the controller, select the same patient and start the test with the same test settings and same eye that was being tested
f) Press the "Recover Data" button located in the lower right corner of the Start Test page
g) Select "Yes" to save the report

⚠ WARNING: To prevent permanent loss of test data, DO NOT TOUCH THE TEST DEVICE OR CLICKER between selecting 'Start Test' and 'Stop Test'.

h) Go to the Test page on the Controller and select '**Resend data'** as shown in **Figure 40**.

In this way, all the former data can be seen on the controller and is sent to the webserver on completion of the test. The connect button on the test page appears green when the connection is successful as shown in **Figure 35: Connect button appears green on successful connection.**

Figure 35: Connect button appears green on successful connection

5.5 View of Dashboard when ready for test

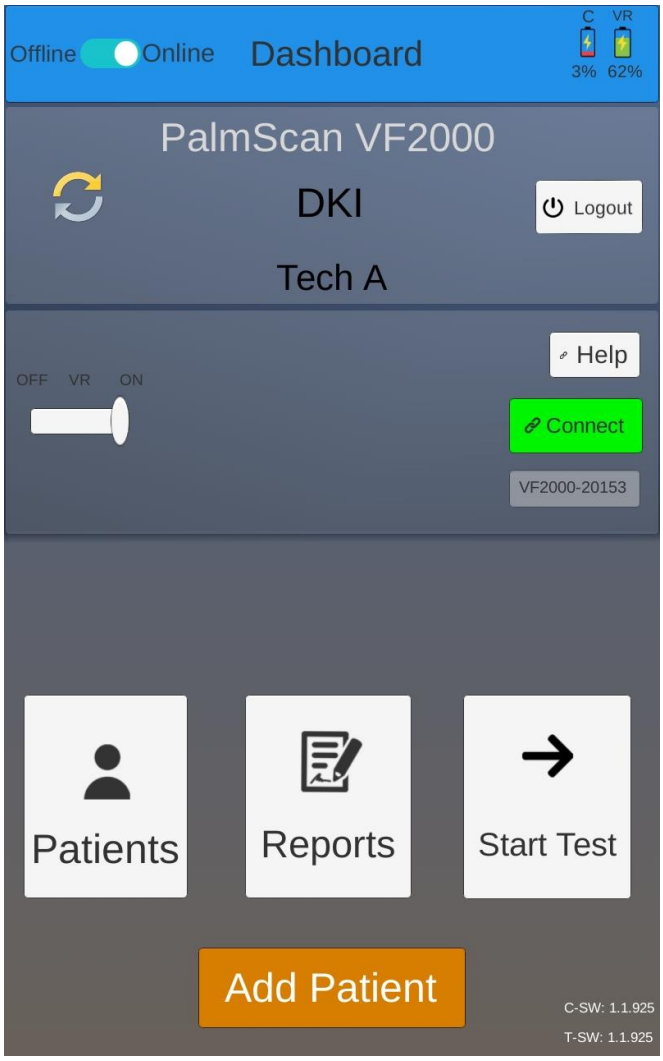


Figure 36: This page shows the options of Selecting Patients, Adding Patients, Looking at Reports, Starting a Test.

5.6 Selecting/ Viewing a Patient's record

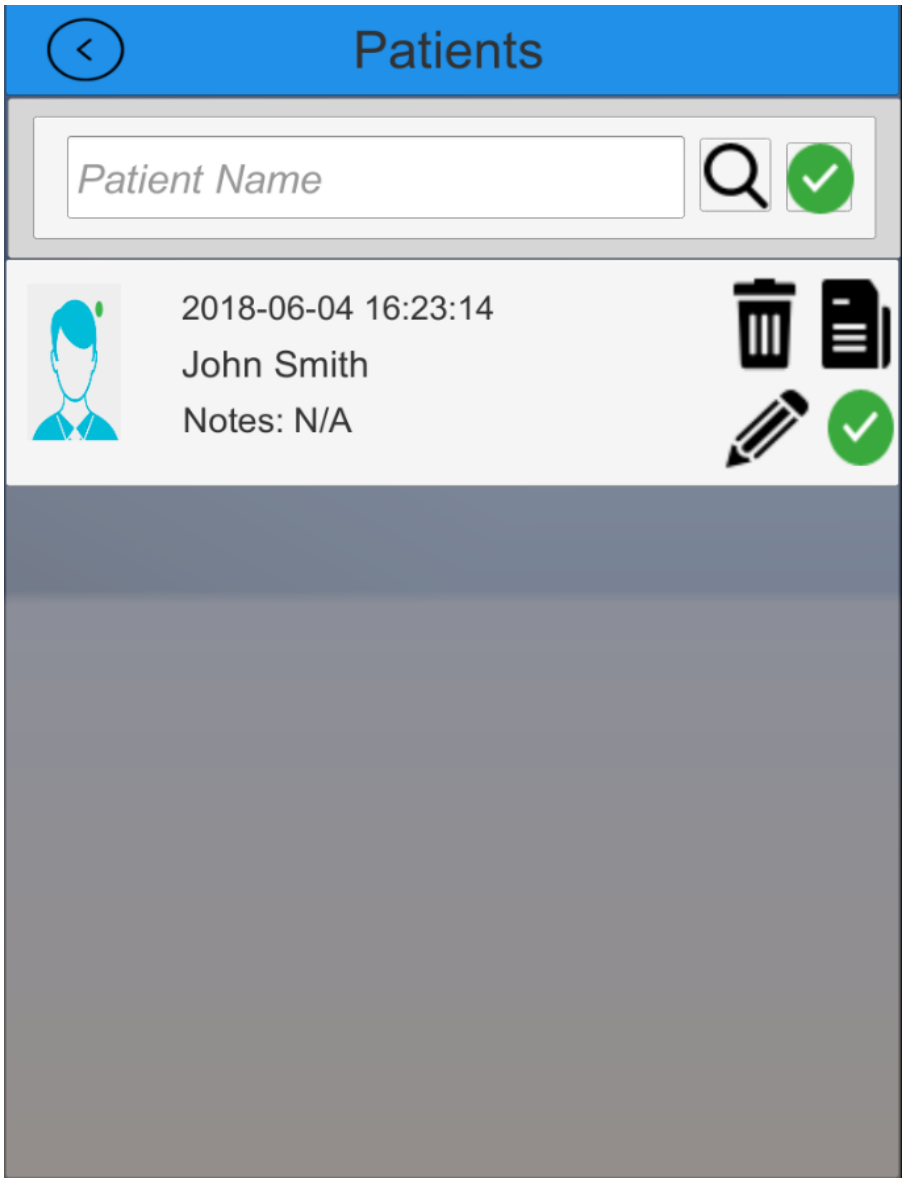


Figure 37: Patient "Add" or "Select" will show a patient page

From the dashboard, select the patient tab at the bottom left. A patient page will open and show the list of patients as shown above **Figure 37: Patient "Add" or "Select" will show a patient page.** The () icon is to delete the selected patient from the controller, () Icon is used to view the selected patient's reports, () Icon is to edit any information about the patient and () Icon is to indicate an active patient.

5.7 Access Test Reports of Patients

From the dashboard, select the reports button at the bottom of the page. The options are shown below in **Figure 38: Reports Display Page**.

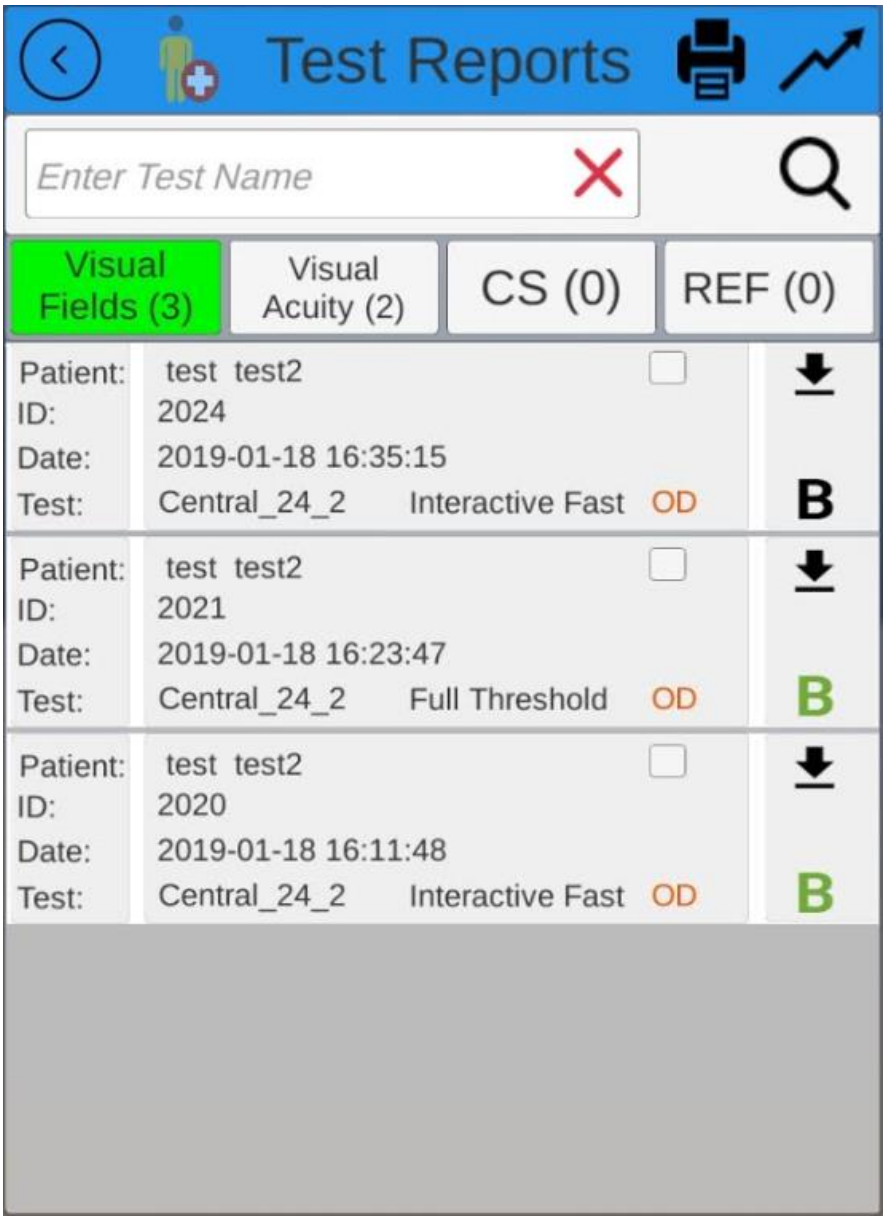


Figure 38: Reports Display Page

On selecting the '**Reports**' button, the test reports of all the active patients are displayed as in Figure 38: Reports Display Page. The ( ) Icon is used to download the reports on the controller. The (B) button is automatically selected (hence the "B" appears green) for threshold tests. It indicates that the test report in question is good and can be used for progression analysis. It needs to be turned off, by clicking on it (appears grey) by a staff member, in case discrepancies occur during the test such as- patient falling asleep, test report generated by mistake, etc.

5.8 How to Start a Test for a Patient

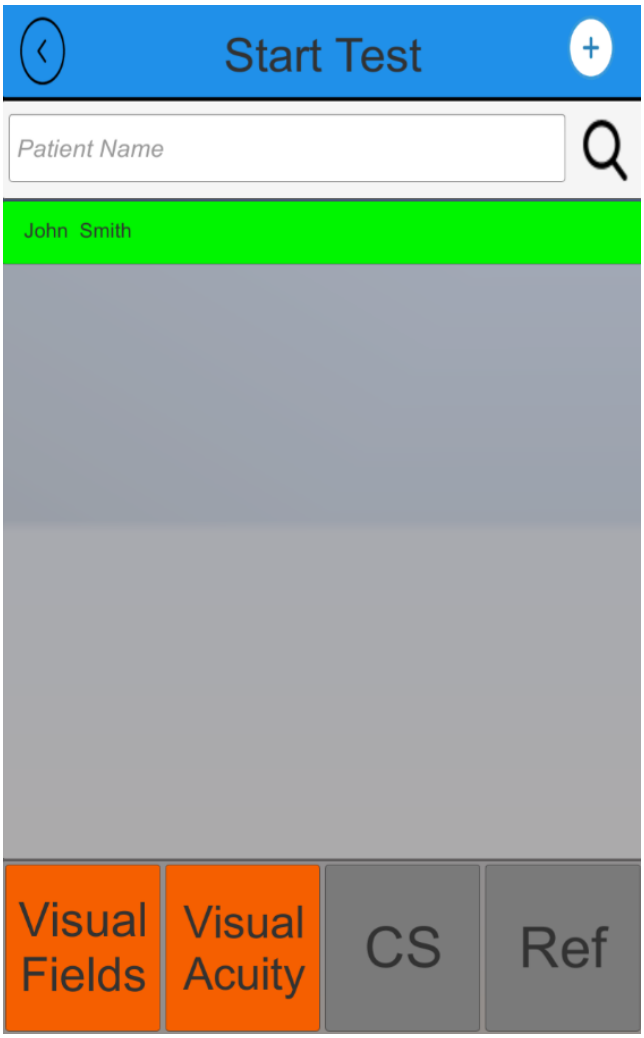


Figure 39: Start Test Page, Highlight the Patient Name and Select Test Type

In the controller page Select "***Start Test***". The Start page will open as shown in **Figure 40: Test options**.

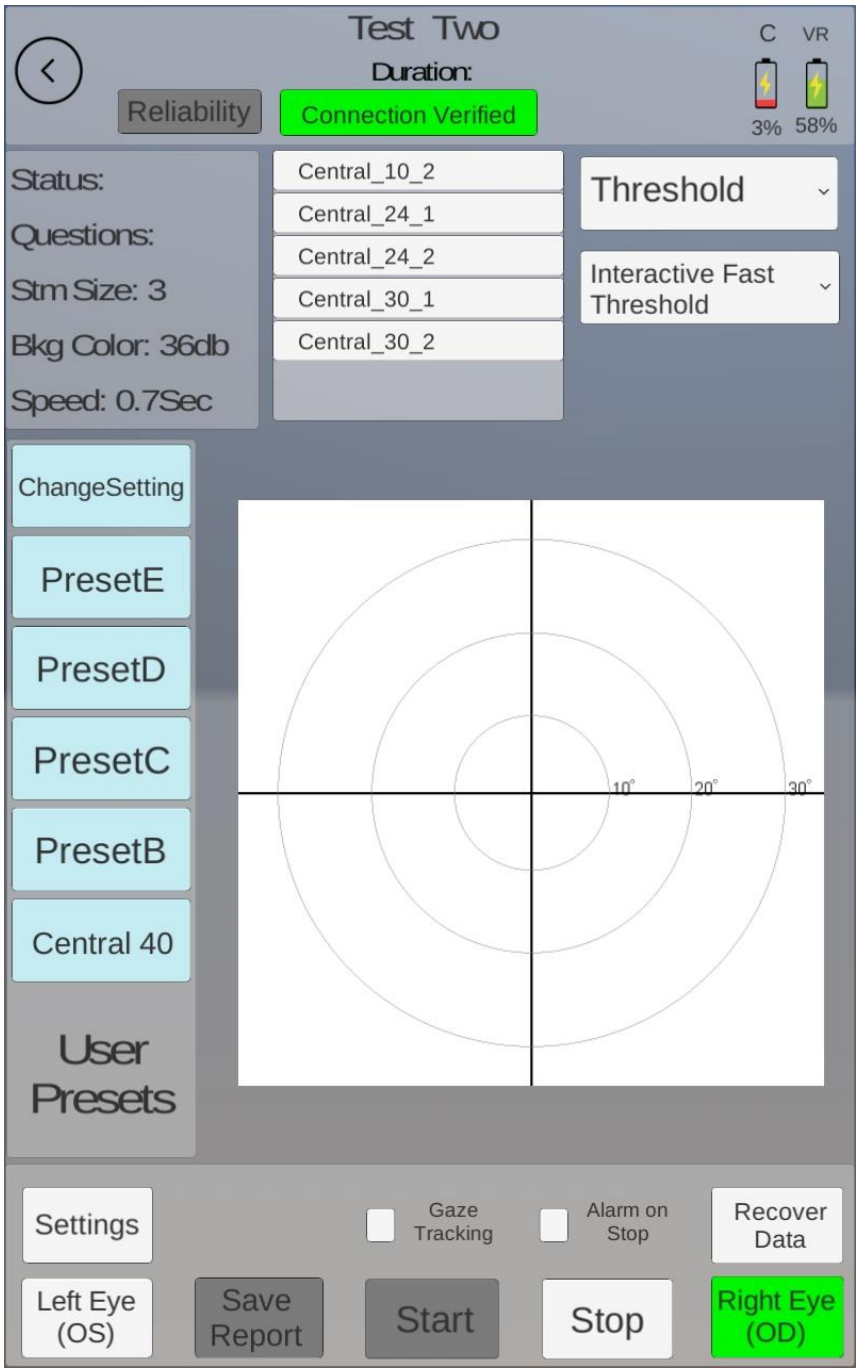


Figure 40: Test options

To start a test for a new patient, a patient can be added by pressing the ( ) icon on the top right corner of the page as shown in **Figure 41: Add a patient to start a test.**

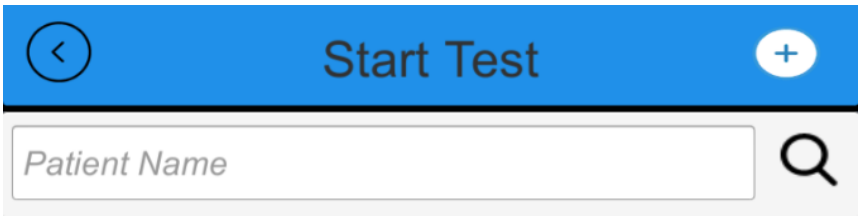


Figure 41: Add a patient to start a test

Note: A few adjustments need to be made before the test can be conducted:

- The patient can perform the test with their prescription glasses on (up to 16 cm (6.3 inches) width as seen in Figure 4: Prescription Glasses Fit) or use the trial lens adaptors provided to adjust the prescription to be able to see clearly.
- Enabling the “Eye Tracking” option will ensure that the patient is paying attention during the test, by tracking the movement of the eyeball. This is recommended for good test results.
- If the Eye Tracking is on, before the test starts there will be a calibration as seen in Figure 18: Eye Tracking Calibration. The patient will be asked to look at each corner of the headset screen. The test will then proceed and if the patient looks away from the red focus dot, the test will pause. If eye tracking is turned off, the patient just keeps looking at the red dot and presses the clicker button twice to start the test and continues to look at the red dot during the test.

The following messages/instructions are displayed to ensure that the devices are active and ready to start the test:

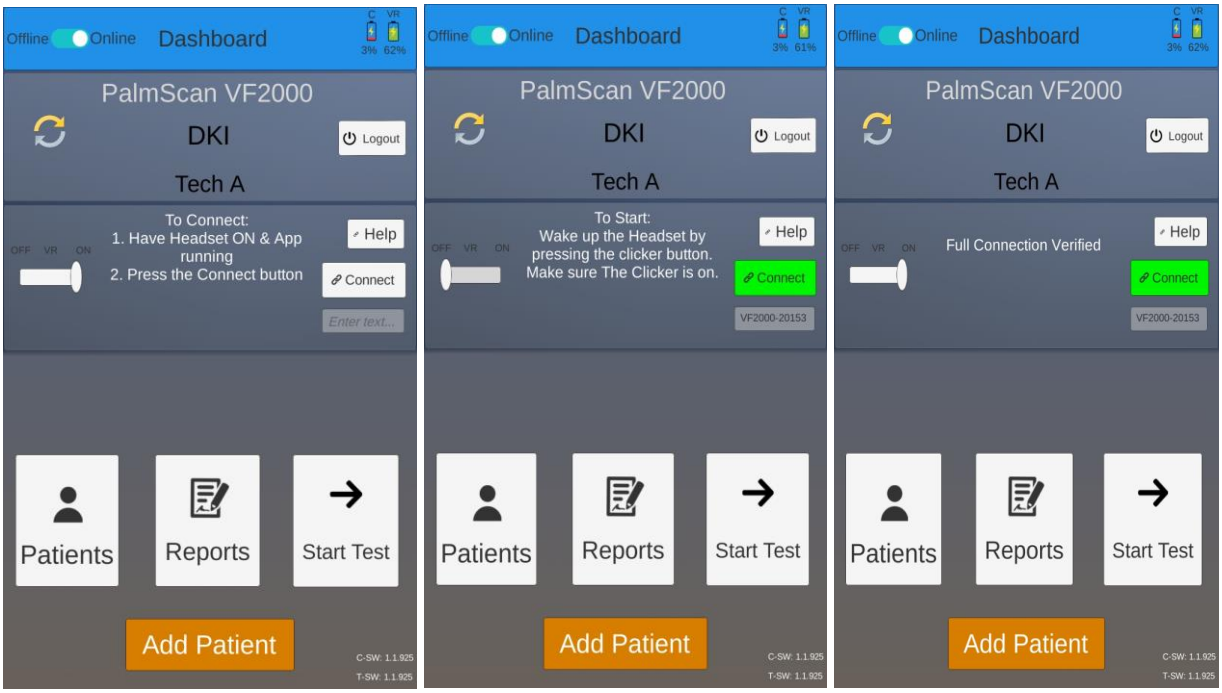


Figure 42: Display instructions to ensure devices are active and ready to start the test

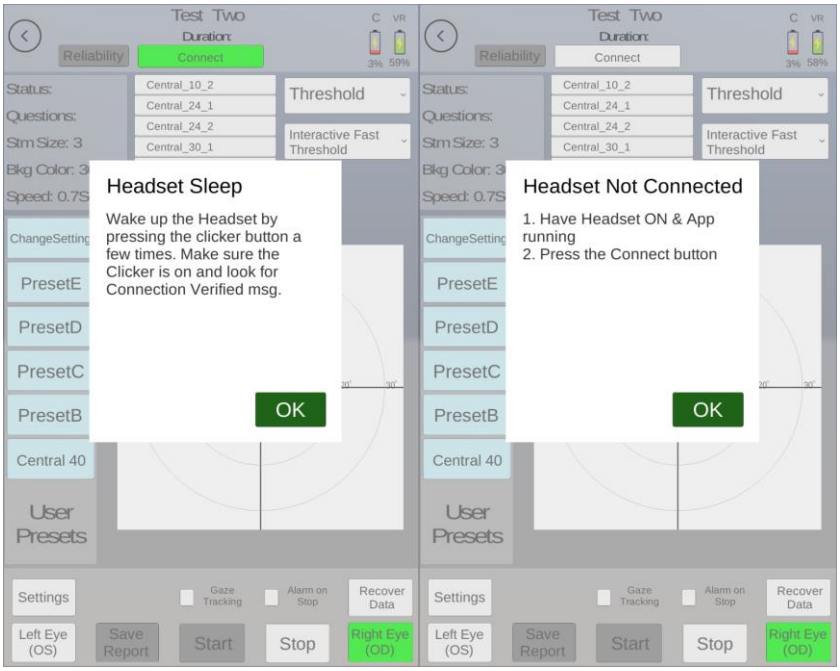


Figure 43: Instructions as Message pop ups to ensure the device headset is active and connected

Master Record Error: If 24-2 test on the Controller is selected, and a message that Master Record error pops up

Go back to the Dashboard page, Log Off from your account (this can only be done when you have Wi-Fi connection) and then Log back in. Wait for the Auto-Sync to complete. Go to the VF settings and click on 'Get Master Records' and wait for the 'Master Record Download Complete' notification. Go back up to the Dashboard page wait for 1 minute and try to start the 24-2 test again.

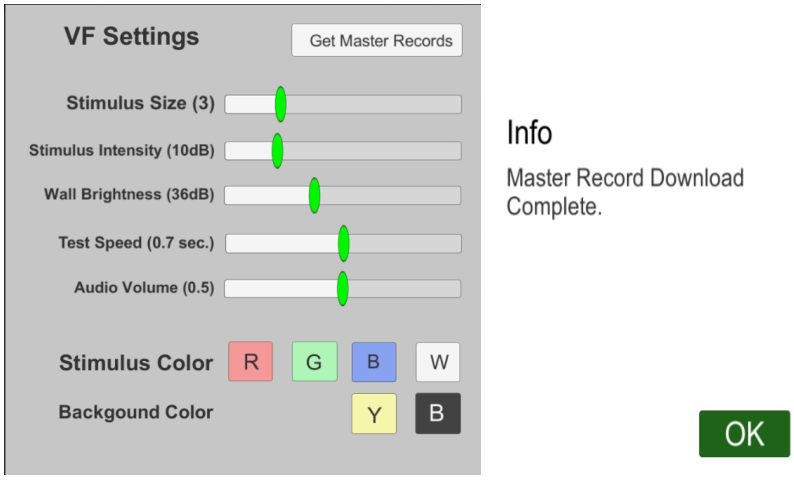


Figure 44: Resolving Master Record Error

Disease Category	Test(s) Recommended
General Screening	Central_40_point 76_Point_Pattern Central_80_Points Central_166_Points
Full Field Screening	Central_80_Points Central_166_Points
Glaucoma Suspect or Ocular Hypertension	Central_24_1 Central_24_2
Glaucoma	30-2 Standard or Fast Central_24_1 Central_24_2 Central_10_2 76_Point_Pattern Armaly_Central Central_80_Points Central_166_Points
Drug Toxicity	Central_10_2
Neurological Damage	Central_40_point 76_Point_Pattern Neuro 20 Neuro 30
Ptosis	Central_24_2 Central_30_2

Table 1: Disease and Recommended Test

Screening Test Library	Extent of Visual Field Tested/ Number of Points Tested	Application
Central_40_point	30 degrees/ 40 Points	General Screening
	30 degrees/ 64 Points	General, glaucoma, neurological
76_Point_Pattern	30 degrees/ 76 Points	General, glaucoma, neurological
Central_80_Points	30 degrees/ 80 Points	General Screening
Central Armaly	30 degrees/ 84 Points	Glaucoma

Table 2: Screening Test Library

Threshold Test Library	Extent of Visual Field Tested/ Number of Points Tested	Application
Central_10-2	10 degrees/68 Point grid	Macula, retinal, neurological, advanced glaucoma
Central_24-2	24 degrees/54 Point grid	Glaucoma, general, neurological
Central_30_2	30 degrees/76 Point grid	Glaucoma, retinal, neurological, general
Central_30_1	30 degrees/76 Point grid	Glaucoma, retinal, neurological, general

Table 3: Threshold Test Library

5.9 Selecting the type of test and the test eye

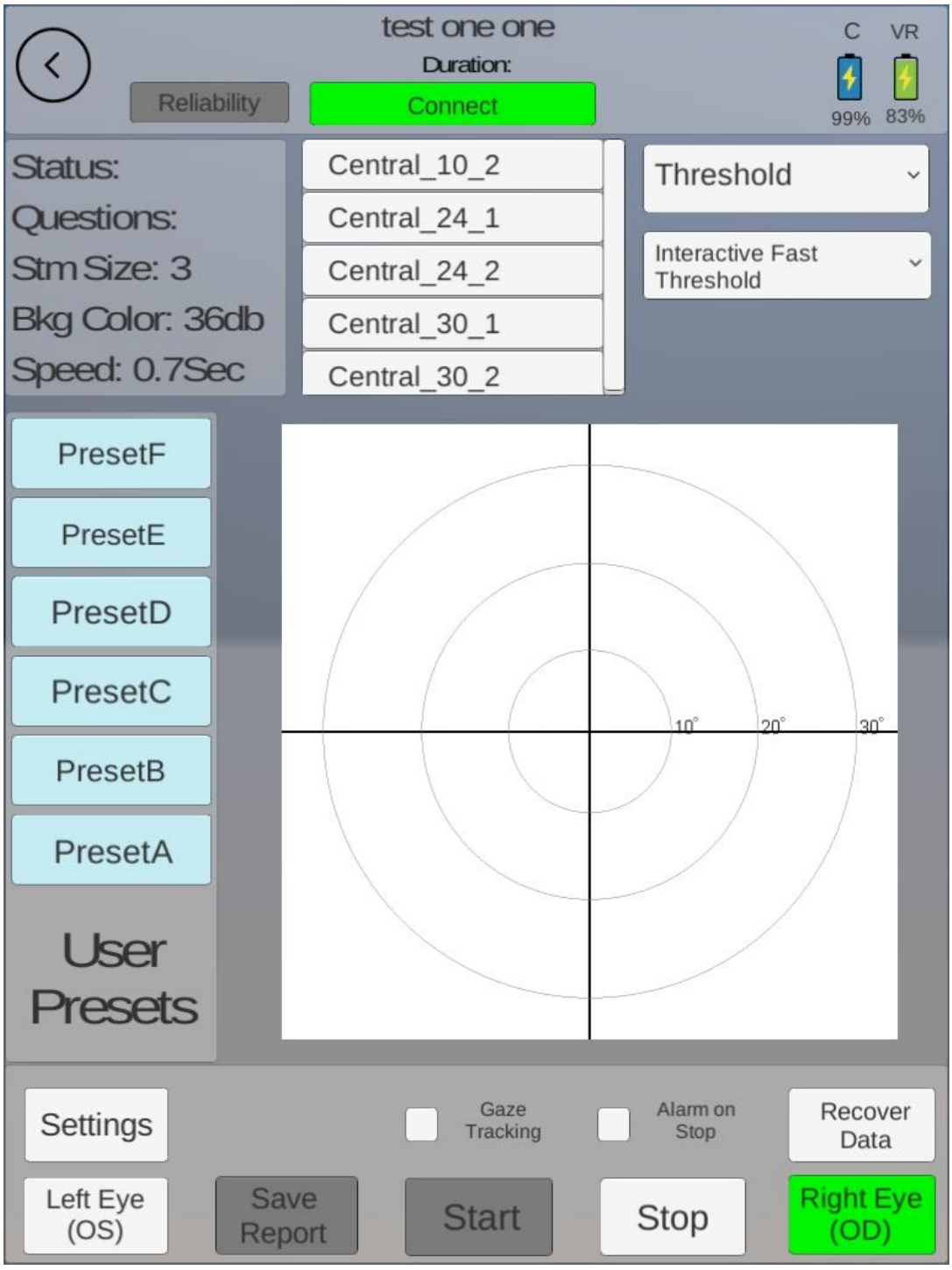


Figure 45: Visual Field Page Right Eye (OD) Selected

Selecting "*Visual Fields*" test selection and the Visual Fields Test Page will open up as shown in Figure 45: Visual Field Page Right Eye (OD) Selected**.**

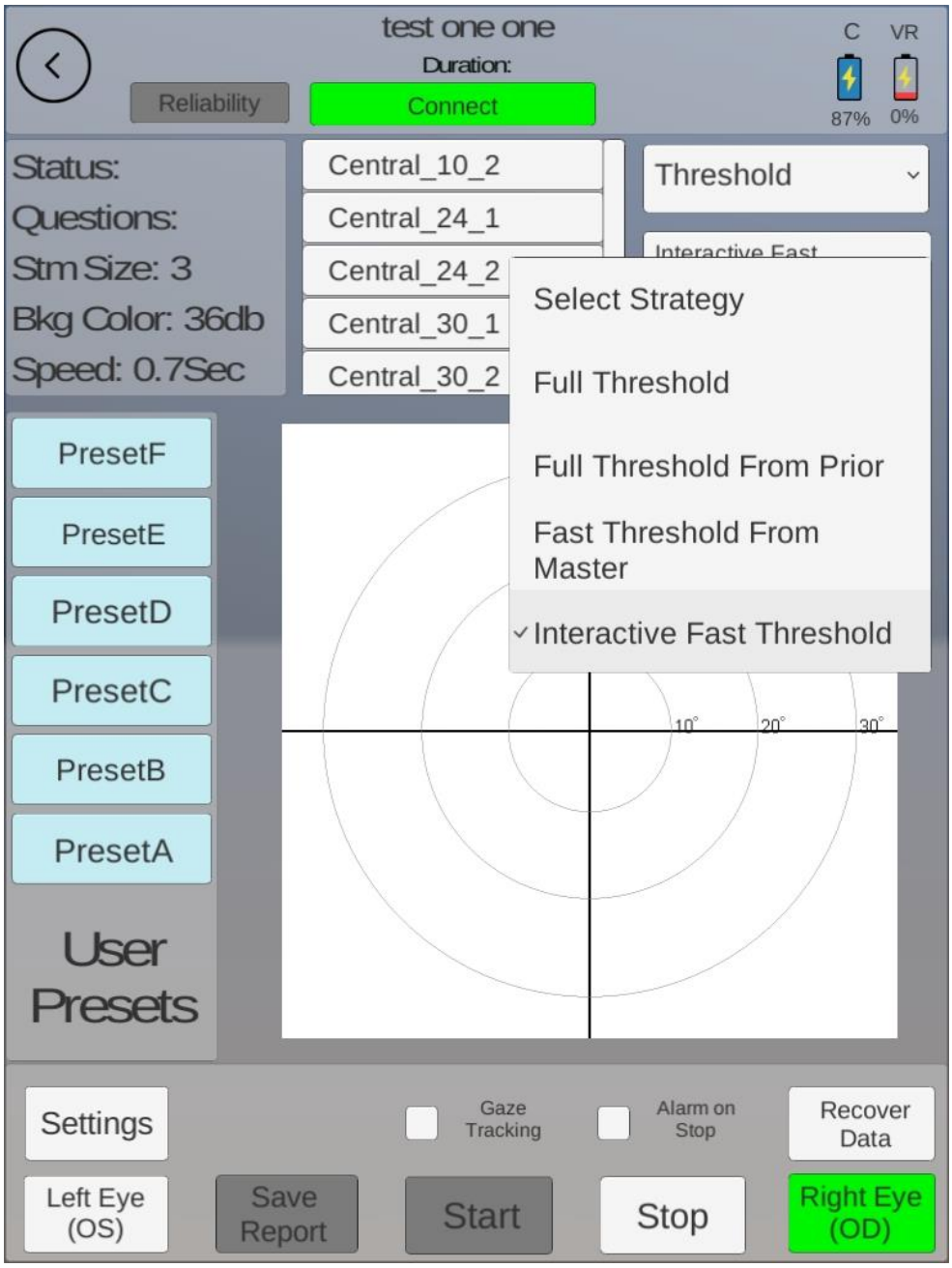


Figure 46: Visual Field Test Page Select type of Strategy

The test options are found as in Figure 46: Visual Field Test Page Select type of Strategy. The Selections are:

- Full Threshold
- Full Threshold From Prior Data
- Full Threshold From Master Data
- Interactive Fast Threshold

More explanation on the type of strategy is given in chapter 6.

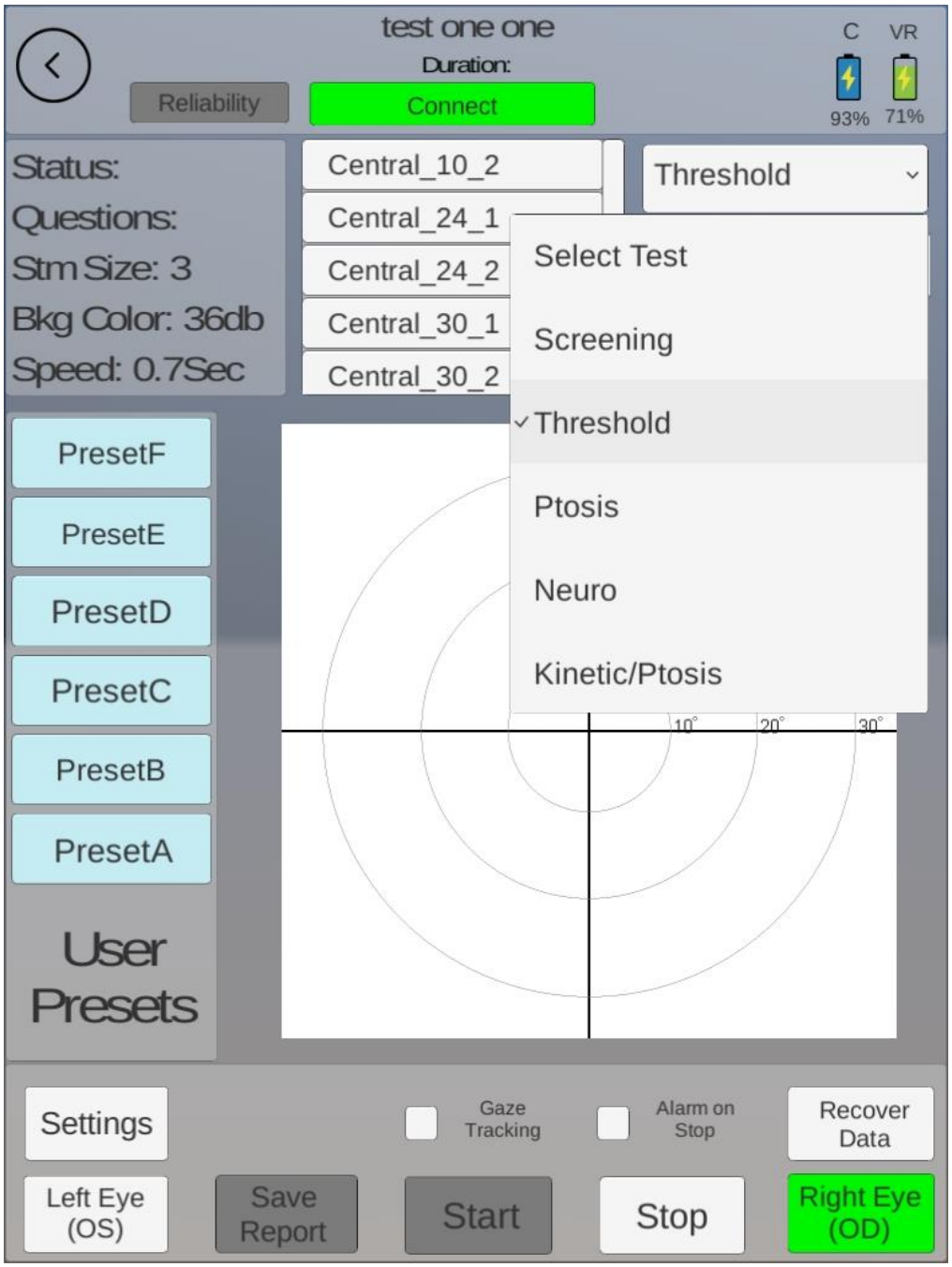


Figure 47: Select Test drop down Selections

As shown here, the selection options are:

- Screening
- Threshold
- Ptosis
- Neuro

Make the test selection from the list above. More explanation of the test is in chapter 6.

6. Tests

6.1 Screening Test Strategy

This test is designed to screen intensities of light that can be seen by the patient. It has 4 types of strategies as mentioned below.

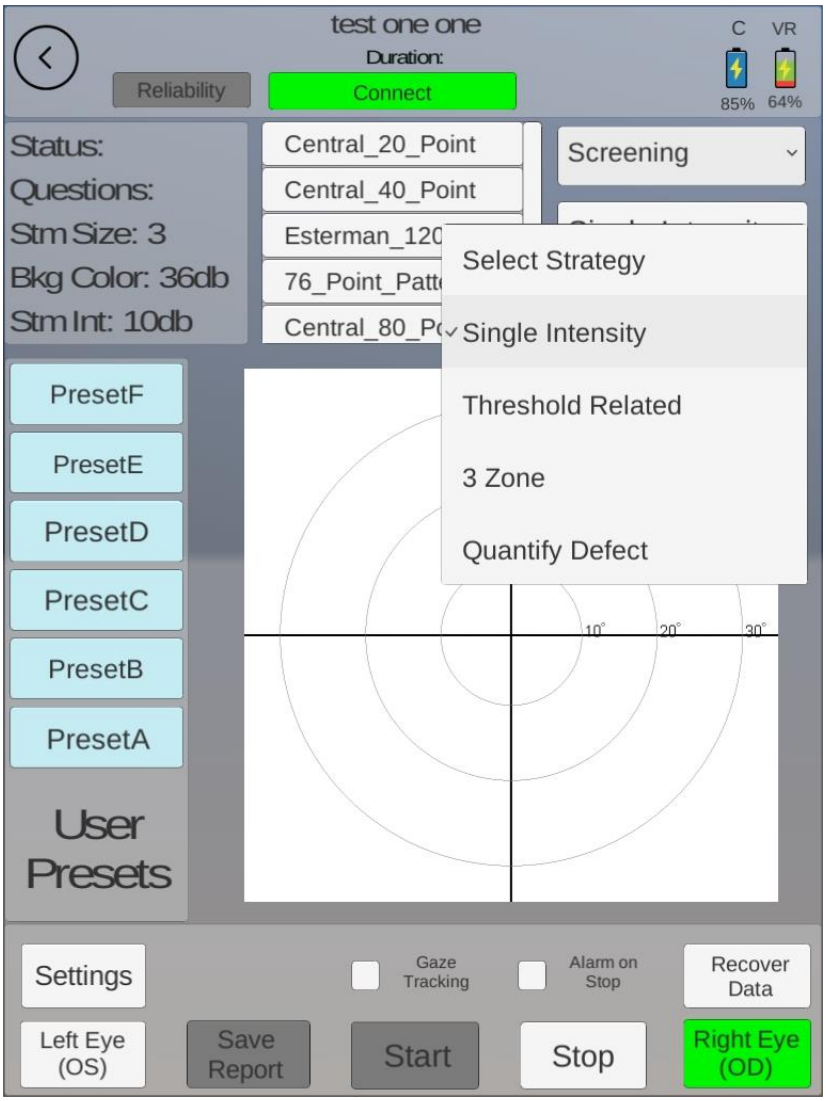


Figure 48: Screening Test Strategy drop down options

As shown in **Figure 48: Screening Test Strategy drop down options**, the selection options are:

- Single Intensity
- Threshold Related
- 3 Zone
- Quantity Defect

6.1.1 Single Intensity

A preset value of intensity is selected based on the strategy chosen. Different points with the same intensity are shown at different time points. If the patient does not press the clicker for a single point in the chart, it is shown again. If the point is still not seen by the patient, it is marked red on the chart. After the completion of the selected test, a test report is generated as shown in **Figure 49: Test report for Central 40, Single Intensity.**

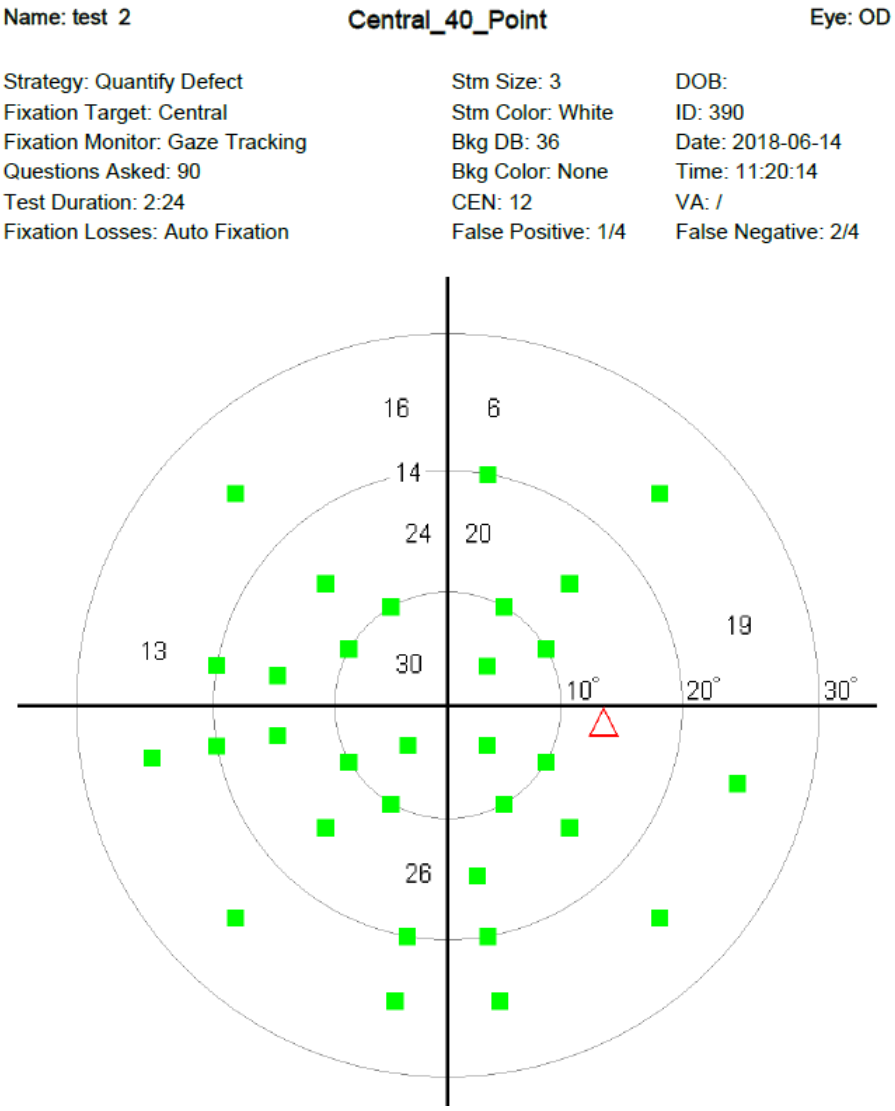


Figure 49: Test report for Central 40, Single Intensity

- -Point is seen

6.1.2 Threshold Related

In this test, different points are highlighted, based on the pattern shown in the chart of **Figure 50**. The intensity of the points increases with the distance from the center, i.e. the test follows the normal hill of vision of the patient resulting in the construction of visual field contour. The test report is shown in **Figure 50: Test report for Central 40, Threshold related.**

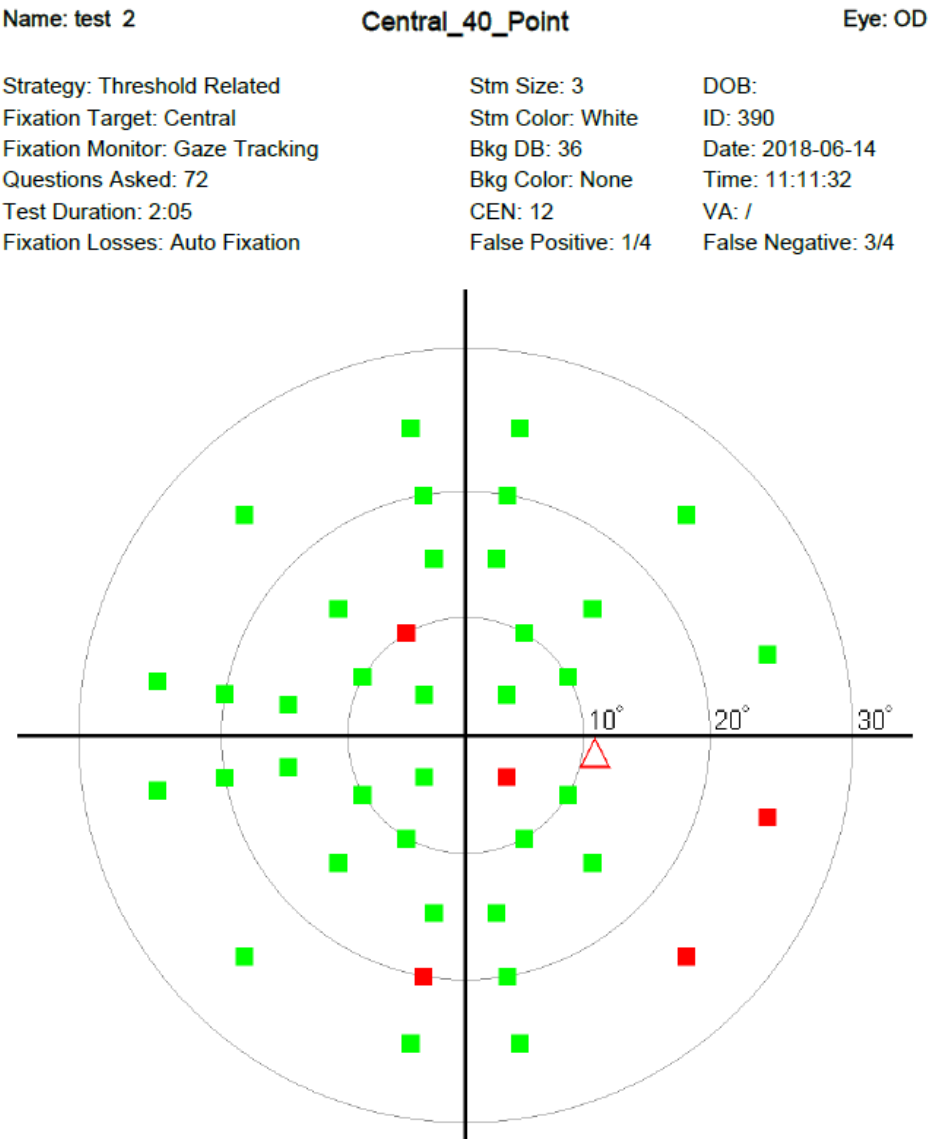


Figure 50: Test report for Central 40, Threshold related

- Point is seen - Point is not seen

6.1.3 Three Zone

In this test, different points are highlighted with a preset value of intensity and shown twice to the patient to see and respond by pressing the clicker. After the second time display of a specific point with no patient response, the intensity of the specific point is increased. If the patient presses the clicker on the point that the intensity is increased, that point is marked in blue, indicating that it can only be observed with higher intensities. If the patient does not detect and respond to the point with higher intensity, it is marked in red, as observed in **Figure 51: Test report for Central 40, 3 zone.**

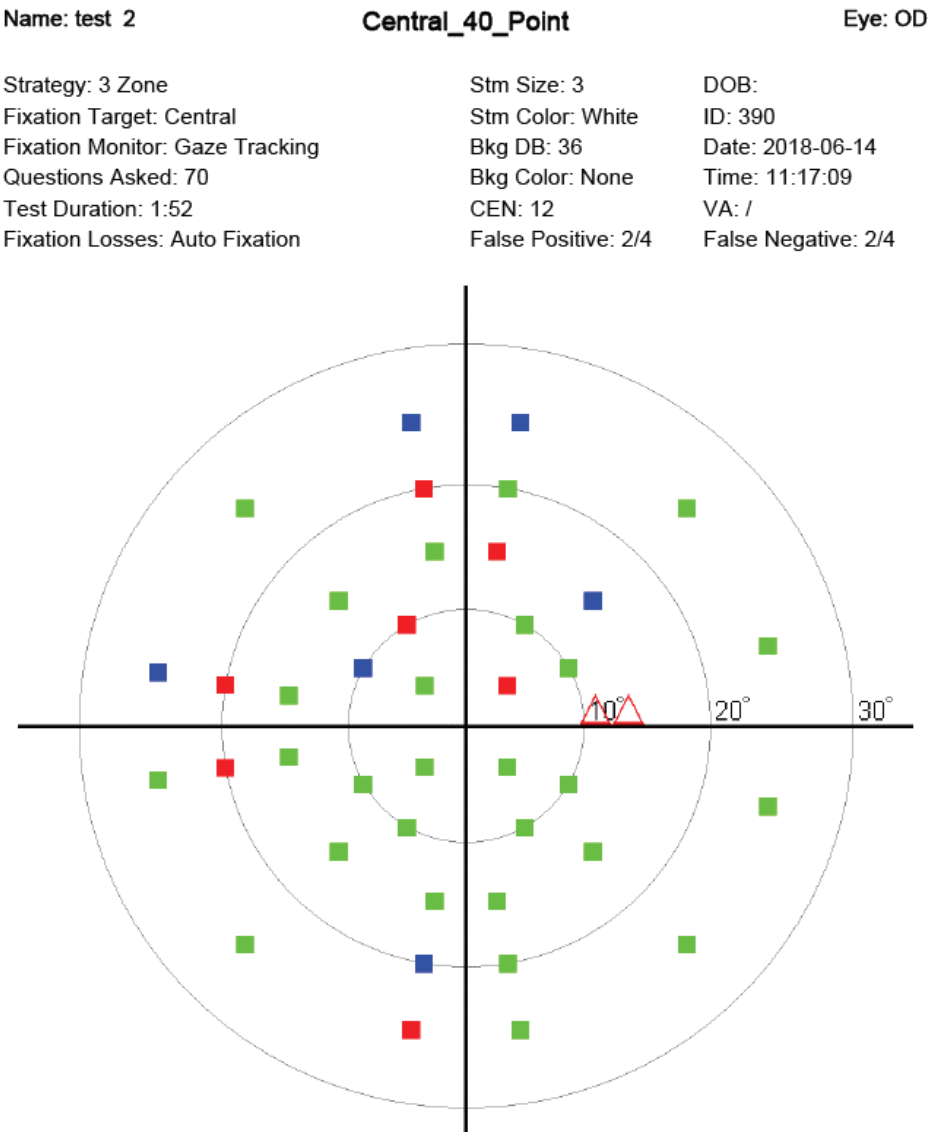


Figure 51: Test report for Central 40, 3 zone

- Point is seen - Point is seen on increasing brightness - Point is not seen

6.1.4 Quantify Defect

This test, as the name suggests, quantifies in decibels how vision is lacking at the point that is highlighted. A single point based on the chart is highlighted with increasing intensity until the patient can see it and responds by pressing the clicker. The numbers on the chart indicate the decibel values in which the points were observed. The higher the decibel numbers, the dimmer the points will appear. Which means, the vision is better. This is depicted in **Figure 52: Test report for Central 40, Quantify Defect**.

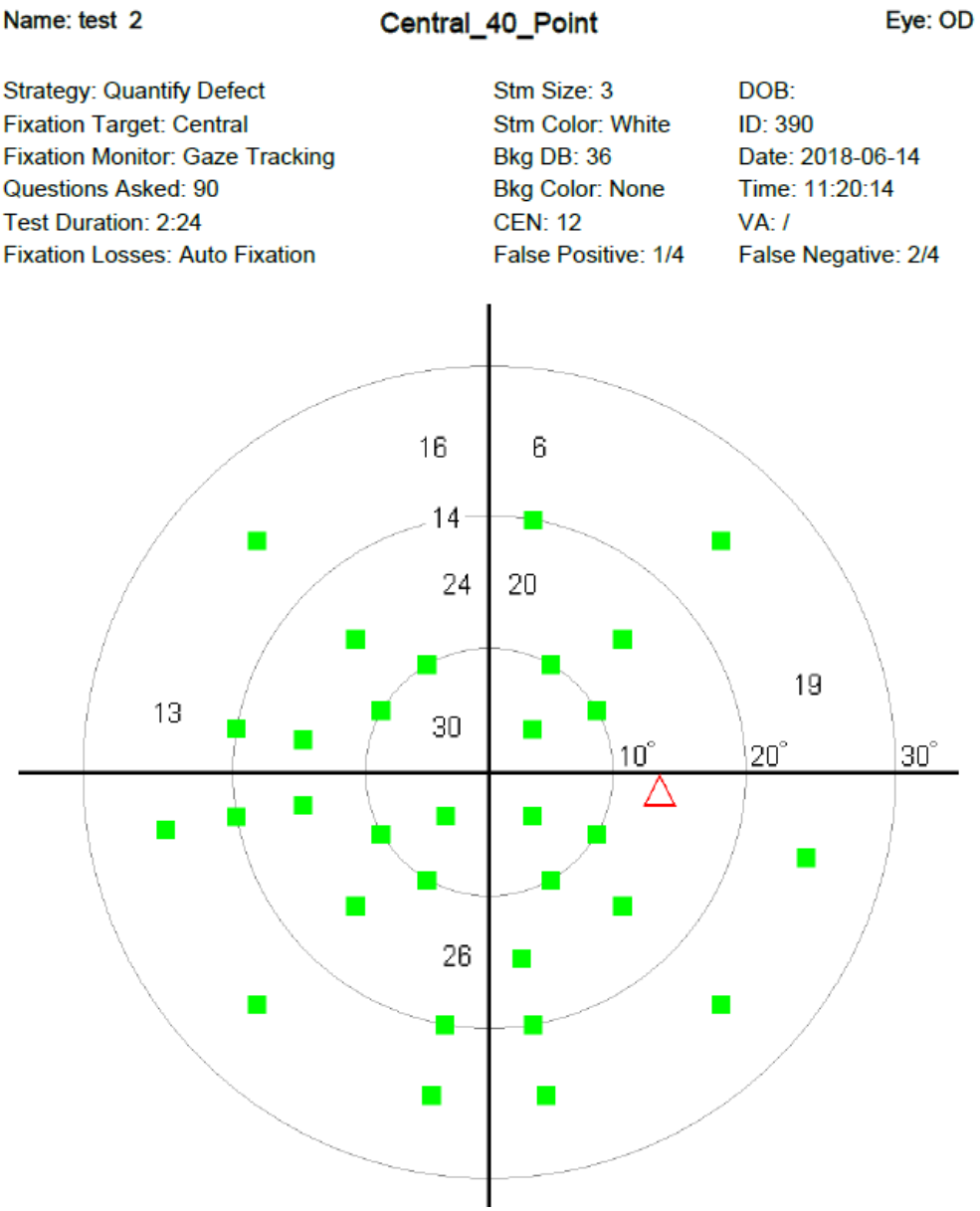


Figure 52: Test report for Central 40, Quantify Defect

■ - Point is seen

6.2 Test Point Patterns for the Screening Test

After selecting the type of test, select the Strategy from the drop-down menu. i.e., **Figure 53: Screening with Single Intensity, Armally_Central Pattern** depicts "***Screening***" Test with a strategy of "*Single Intensity*". Note each strategy will have a list of options for patterns to select.

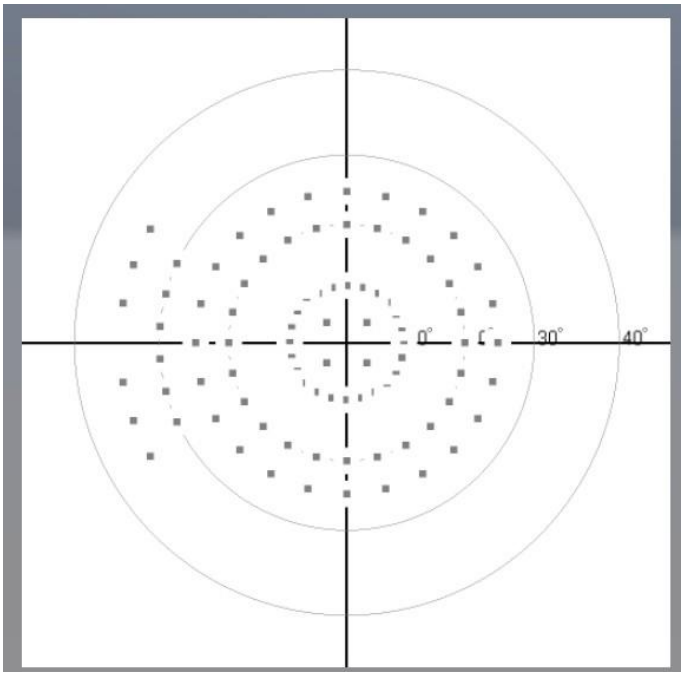


Figure 53: Screening with Single Intensity, Armally_Central Pattern

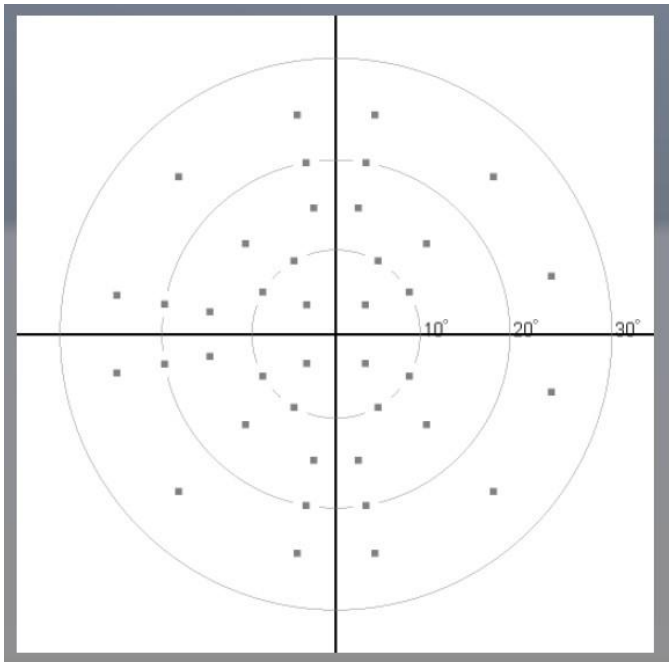


Figure 54: Screening with Single Intensity, Central_40_Point_Pattern

The Test shown here, is a Screening with Single Intensity, Central_40_Point_Pattern is the page displayed for "***Screening****"* Test with a strategy of "*Single Intensity*" and test pattern of "***Central_40_Point***" selections.

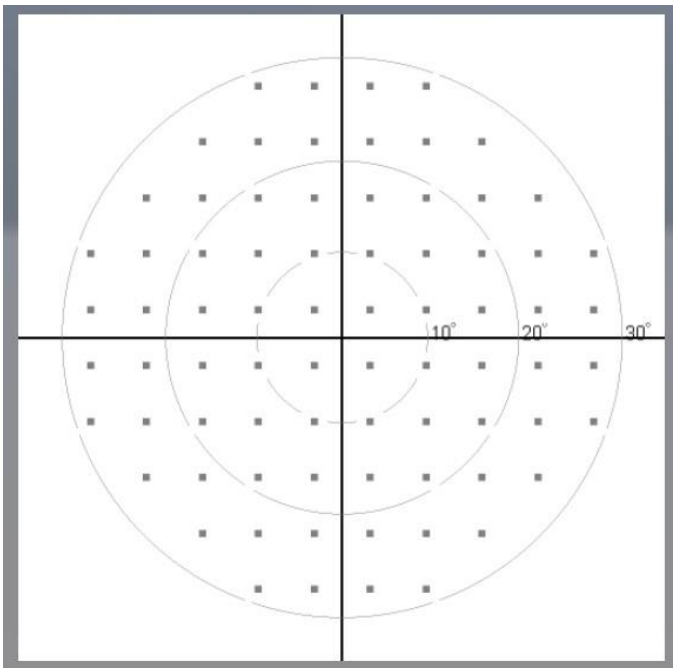


Figure 55: Screening with Single Intensity, 76_Point_Pattern

The Test shown in **Figure 55: Screening with Single Intensity, 76_Point_Pattern**, is a Screening with Single Intensity, 76_Point_Pattern is the page displayed for "***Screening****"* Test with a strategy of "*Single Intensity*" and test pattern of "***76_Point_Pattern***" selections.

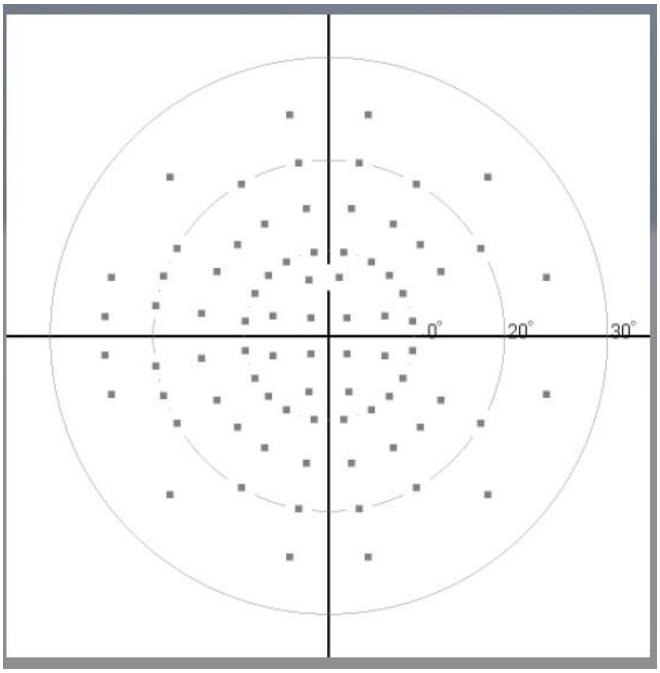


Figure 56: Screening with Single Intensity, Central_80_Point Pattern

The Test shown here is the page displayed for "***Screening****"* Test with a strategy of "***Single Intensity***" and a *"****Central_80_Point Pattern****"* selections.

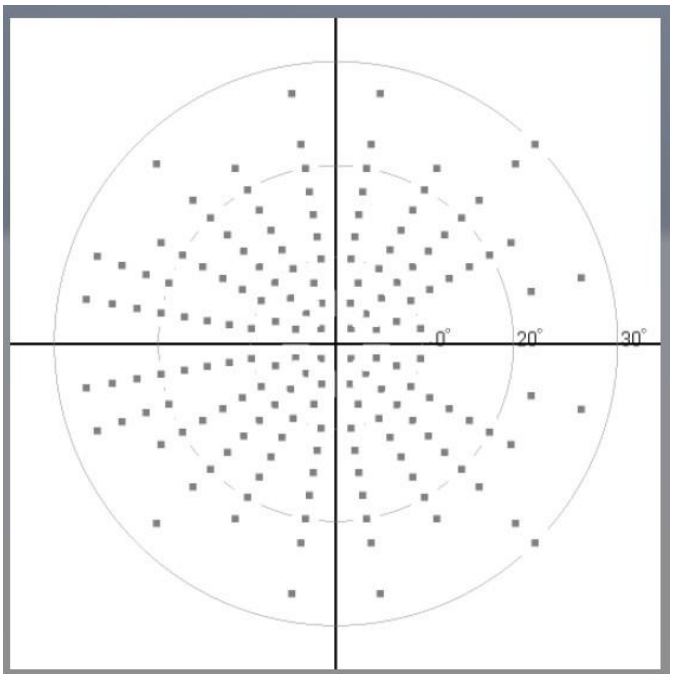


Figure 57: Screening with Single Intensity, Central_166_Point Pattern

The Test shown in **Figure 57: Screening with Single Intensity, Central_166_Point Pattern** is the page displayed for "***Screening***" Test with a strategy of "***Single Intensity***" and a Pattern selection of "***Central_166_Point****"*.

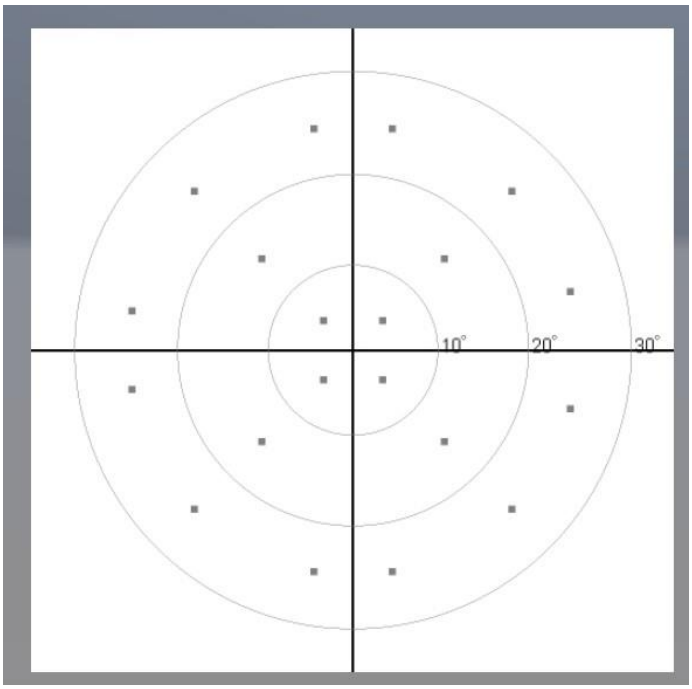


Figure 58: Single Intensity, Central 20 Point

The Test shown in Figure 58: Single Intensity, Central 20 Point is the page displayed for "***Screening***" Test with a strategy of "***Single Intensity***" and a Pattern selection of "***Central_20_Point****"*.

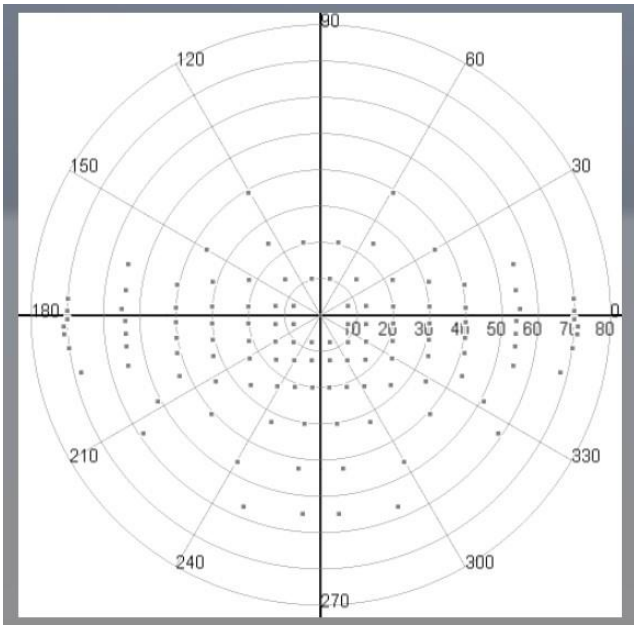


Figure 59: Single Intensity, Esterman 120 Point

The Test shown in **Figure 59: Single Intensity, Esterman 120 Point** is the page displayed for "***Screening***" Test with a strategy of "***Single Intensity***" and a Pattern selection of "***Esterman_120_Point***".

6.3 *Threshold Test Strategy*

The test is designed to test the threshold of intensity that can be seen by the patient. There can be different strategies employed for this test-

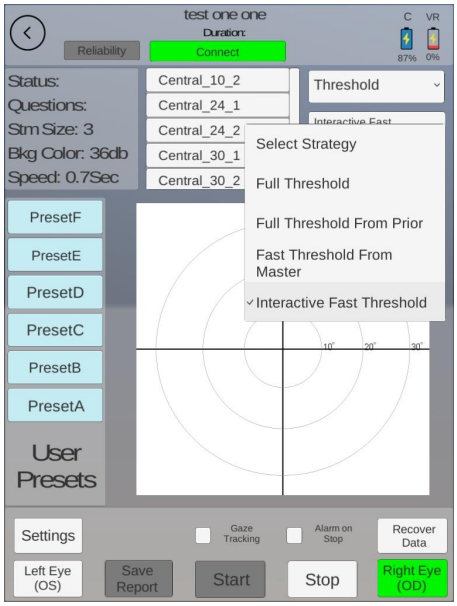


Figure 60: Select Threshold Test

The Threshold test selection as shown here has the following options:

- Full Threshold
- Full Threshold Prior Data
- Fast Threshold Master Data
- Interactive Fast Threshold

6.3.1 *Full Threshold*

This test is designed to find the minimum brightness required for the detection of a light stimulus. The test starts out very dim. If the patient does not respond, the point is gradually increased in brightness until the patient sees and responds. Once the patient responds, the brightness level is saved and the test goes on to test other points.

6.3.2 *Full Threshold from Master*

This test is designed distinctively for each age group. An average is taken for the test amongst a particular age group and each test thereafter is calibrated against the average. During the test, a point is highlighted at 2 decibels higher than the average, and if the patient cannot see it, it is shown again. If missed again, this point is bracketed i.e. the point is highlighted with a range of intensities and the intensity at which the patient can see it is marked on the test. This test can take a while as the number of defects in the eye increases.

6.3.3 Full Threshold from Prior Data

To reduce the time taken for the test, if the patient has done the test before and their reports are still available, the test results are calibrated with the prior test results.

6.3.4 Interactive Threshold Fast

This test takes the least amount of time. The principle behind the test is that 4 points, one in the center of each quadrant is chosen. This point is bracketed, and a value of intensity is assigned to each of them. All the points around are calibrated against that center point. The test uses other information such as patient response or lack of to speed up the test. It will also start at the level of brightness that the patients age group should be able to see instead of starting at the dimmest possible.

6.4 Test Point Pattern for the Threshold Tests

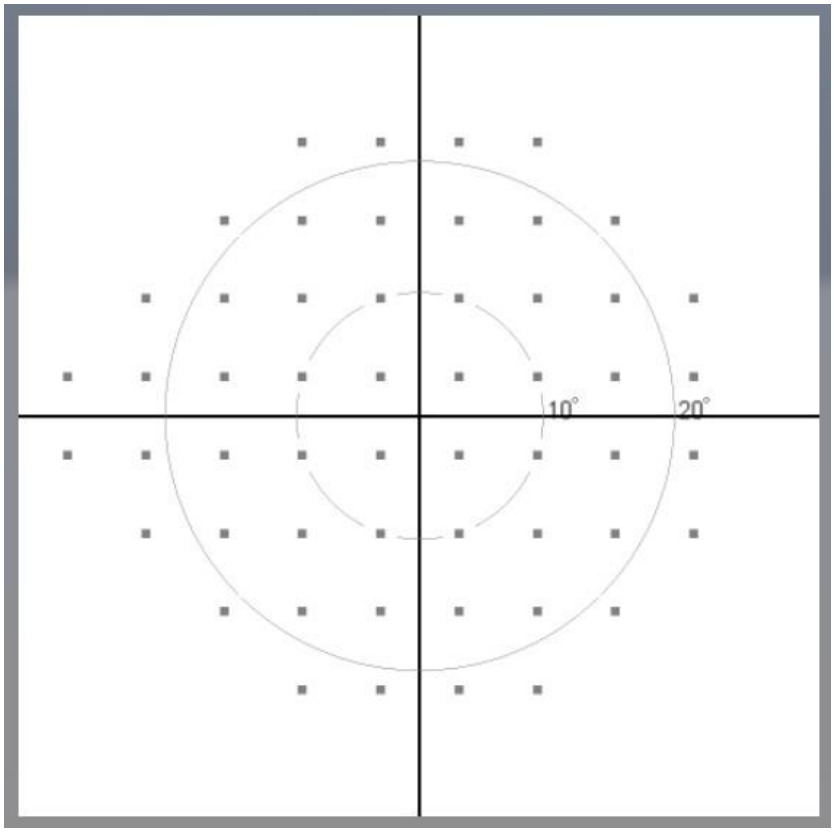


Figure 61: Threshold with Interactive Fast Threshold, Central_24_2 Pattern

The Test shown in **Figure 61: Threshold with Interactive Fast Threshold, Central_24_2 Pattern** is the page displayed for "***Threshold***" Test with a strategy of "***Full Threshold Fast***" and a pattern selection of "***Central_24_2***"

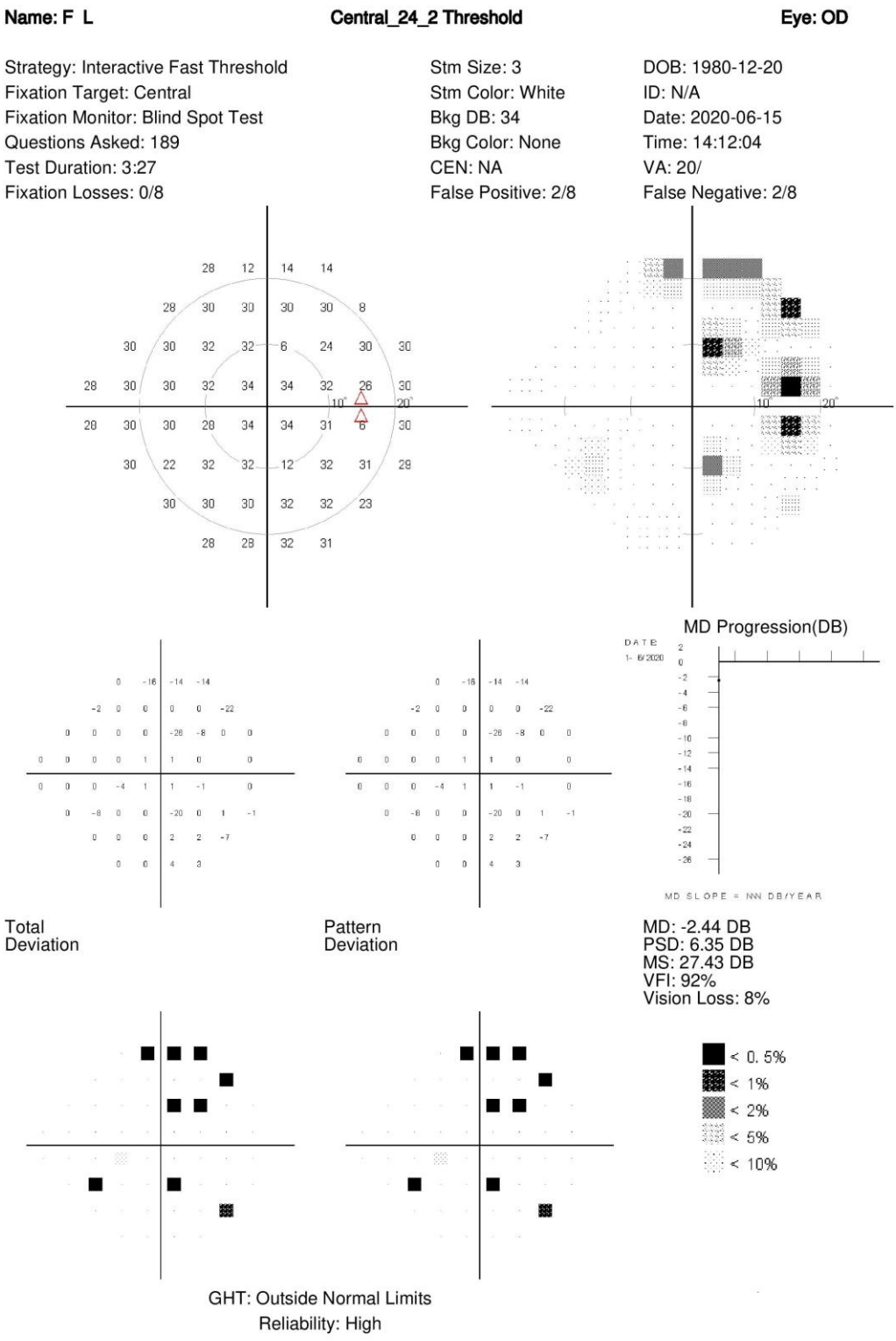


Figure 62: Test Report for Interactive Fast Threshold from Master Central 24_2 Strategy

This report is interpreted as:

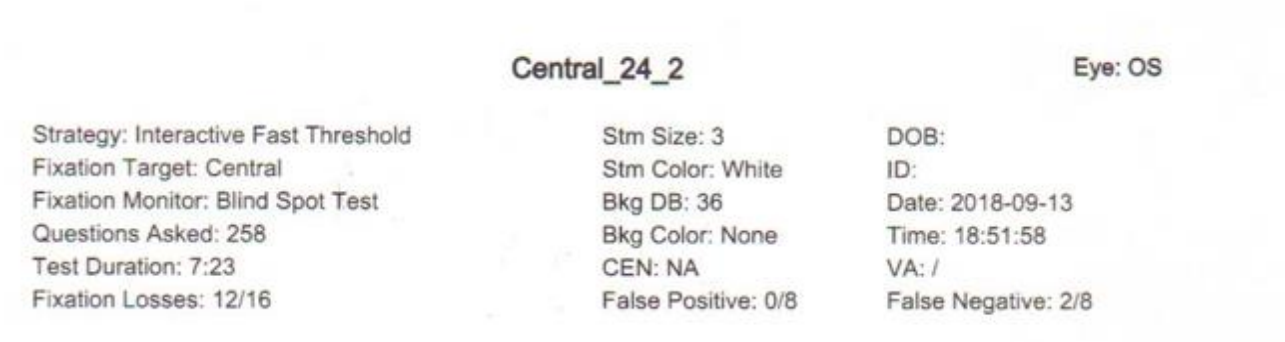


Figure 63: Report Header for Central_24_2

The top part of this report as shown in **Figure 63: Report Header for Central_24_2**, gives basic information about the test, Name of the patient, Strategy used for the test, the eye being tested, duration of test, fixation, patient details, etc.

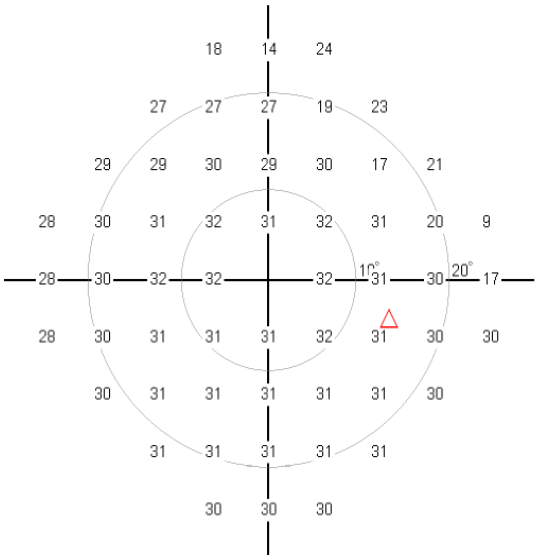


Figure 64: dB Level at Stimulus Points

The section of the chart from **Figure 62** depicted above in **Figure 64**, indicates the patient's ability to see the stimulus. Lower the number, more intensity is required to see the stimulus and lesser the sensitivity in the eye.

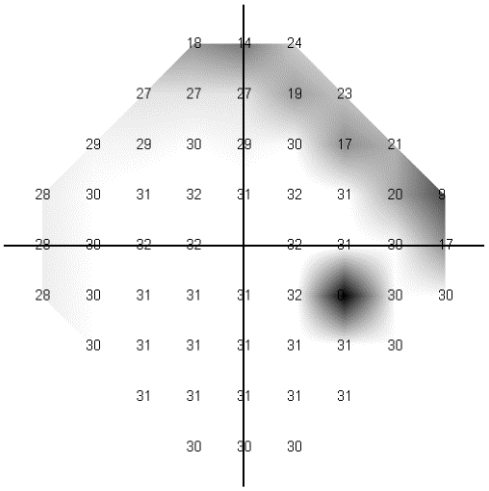


Figure 65: Grey Scale of dB Levels

The section from Figure 62: Test Report for Interactive Fast Threshold from Master Central 24_2 Strategy depicted in Figure 65 above is interpreted as: White area on this chart indicates good/clear vision, the darker areas indicate faulty vision or the blind spot(s) and the grey areas indicate between normal to faulty vision.

There is an option to have a greyscale, classic Humphreys, or a color printout for the dB levels. You can select the printout you want in the settings of the test page.

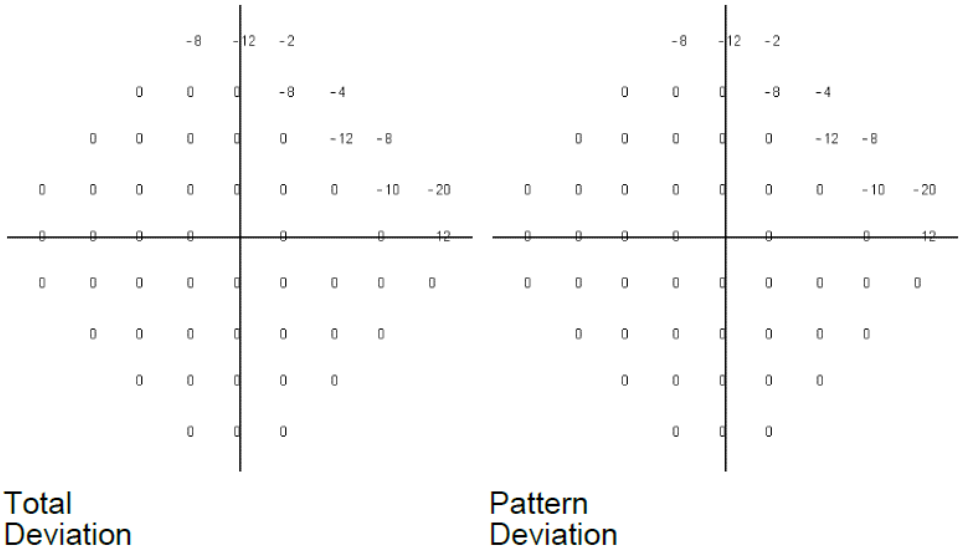


Figure 66: Deviation

The section in **Figure 62: Test Report for Interactive Fast Threshold from Master Central 24_2** Strategy depicted in **Figure 66** above indicates "***Total Deviation***" which indicates the difference between the patient's vision and a normal patient's vision i.e. -2 indicates that this patient can see the point only at 2 dB higher intensity than a normal patient. Indicating worse than normal vision at that point.

"***Pattern Deviation***" is the quantity of defect in the whole eye. Scientifically, it stimulates total deviation when the optimal medium opacity is accounted for. Which means: It is the sum of the mean deviation and square root of the pattern standard deviation.

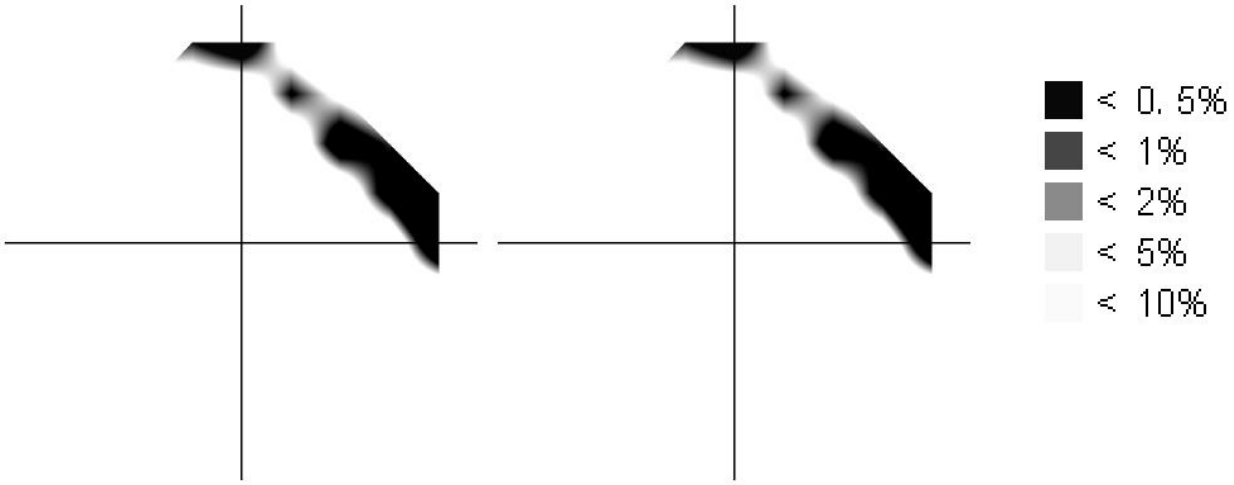


Figure 67: GHT

The graph in **Figure 67** indicates range of vision in the weak areas.

The legend of terms mentioned on the generated report are:
MD - Mean Defect
PSD - Pattern Standard Deviation
MS - Mean Sensitivity
MDf - Mean Defect
Vision Loss - Given as a %

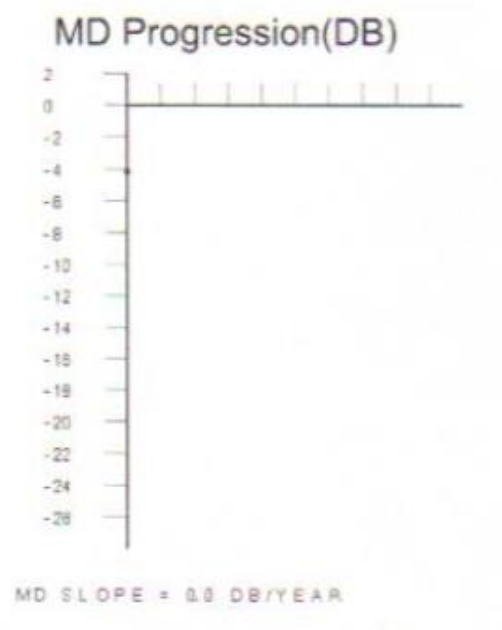


Figure 68: MD Progression

This section indicated in **Figure 69: Threshold with Interactive Fast Threshold, Central_24_1 Pattern** shows the progression of mean defect for a patient. Since this patient is taking this test for the first time, there is only 1 data point indicated in the graph. But, if multiple tests are done for a patient over time, the MD data values are plotted here which is helpful to understand the change in mean defect over time.

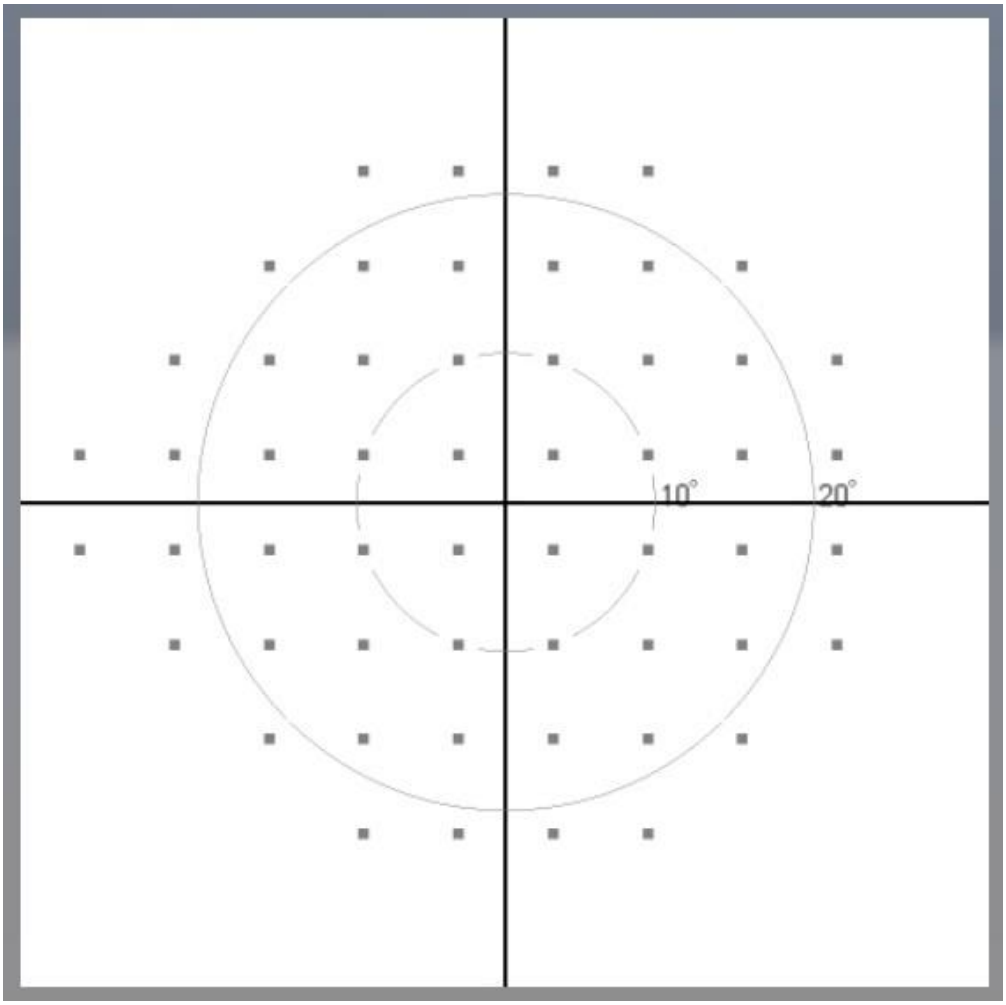


Figure 69: Threshold with Interactive Fast Threshold, Central_24_1 Pattern

The Test page shown in **Figure 62: Test Report for Interactive Fast Threshold from Master Central 24_2** Strategy is the page displayed for Threshold Test with a strategy of Full Threshold Fast and the Central_24_1 Pattern selection. Selecting and running the test shown in figure 54, will generate a test report as shown in **Figure 70: Report for Interactive Fast Threshold from Master Central 24_1** Strategy.

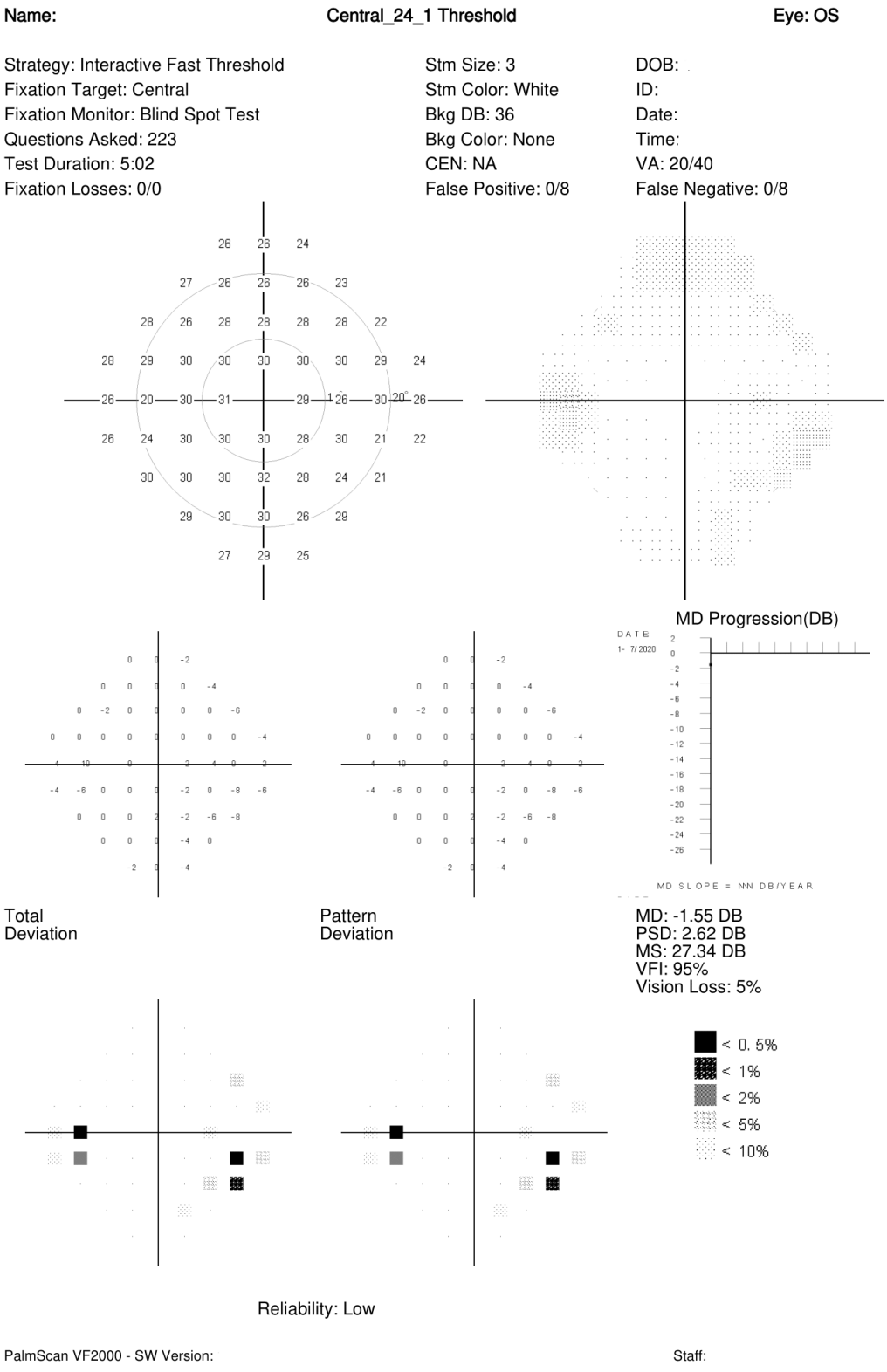


Figure 70: Report for Interactive Fast Threshold from Master Central 24_1 Strategy

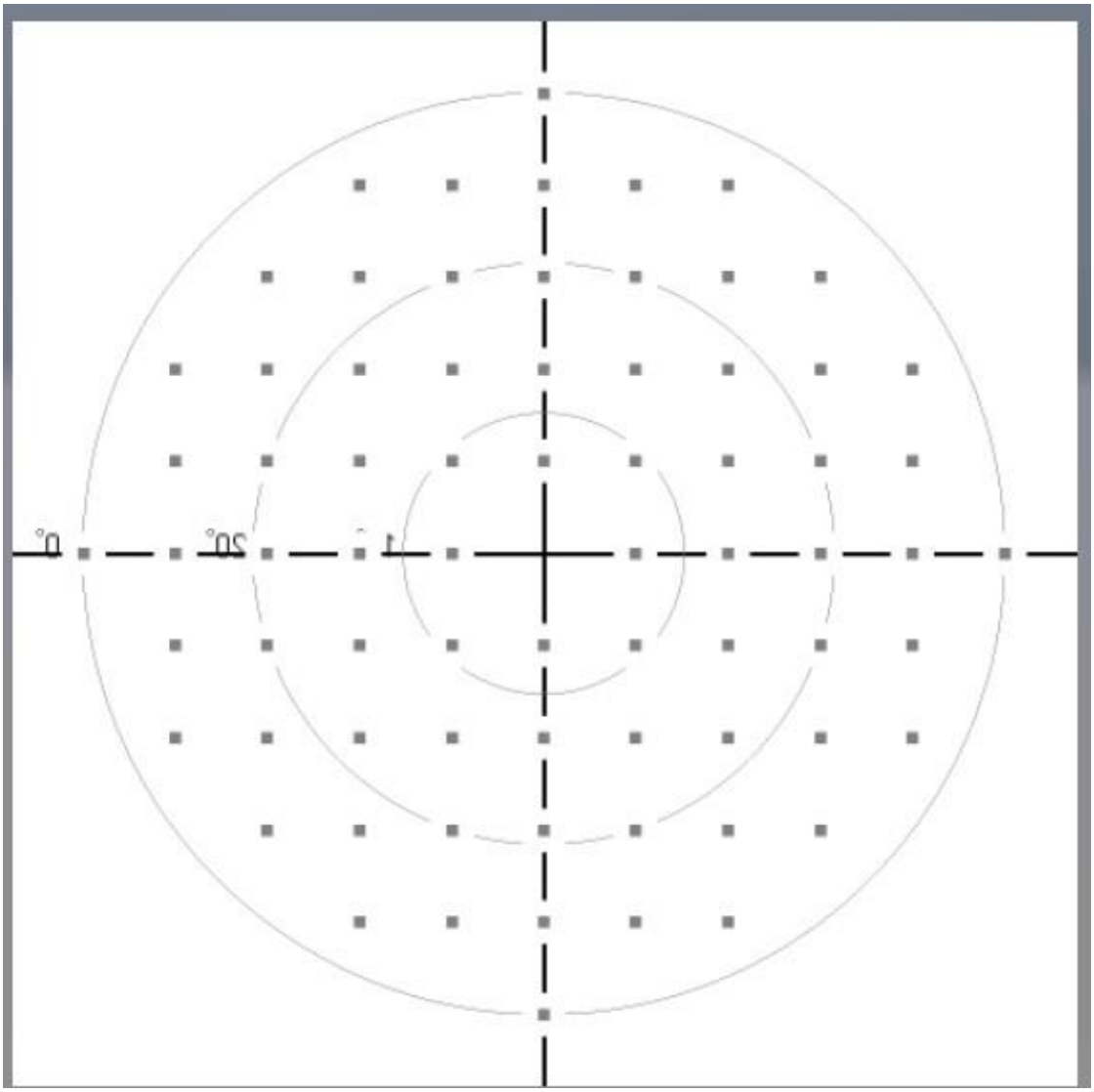


Figure 71: Threshold with Interactive Fast Threshold, Central_30_1 Pattern

The Test page shown in in **Figure 71: Threshold with Interactive Fast Threshold, Central_30_1 Pattern** is the page displayed for Threshold Test with a strategy of Full Threshold Fast with the Central_30_1 Pattern selection.

Selecting and running the test as shown in **Figure 71: Threshold with Interactive Fast Threshold, Central_30_1 Pattern**, will generate a test report as shown in **Figure 74: Test Report for Interactive Fast Threshold from Master Central 30_2** Strategy**.**

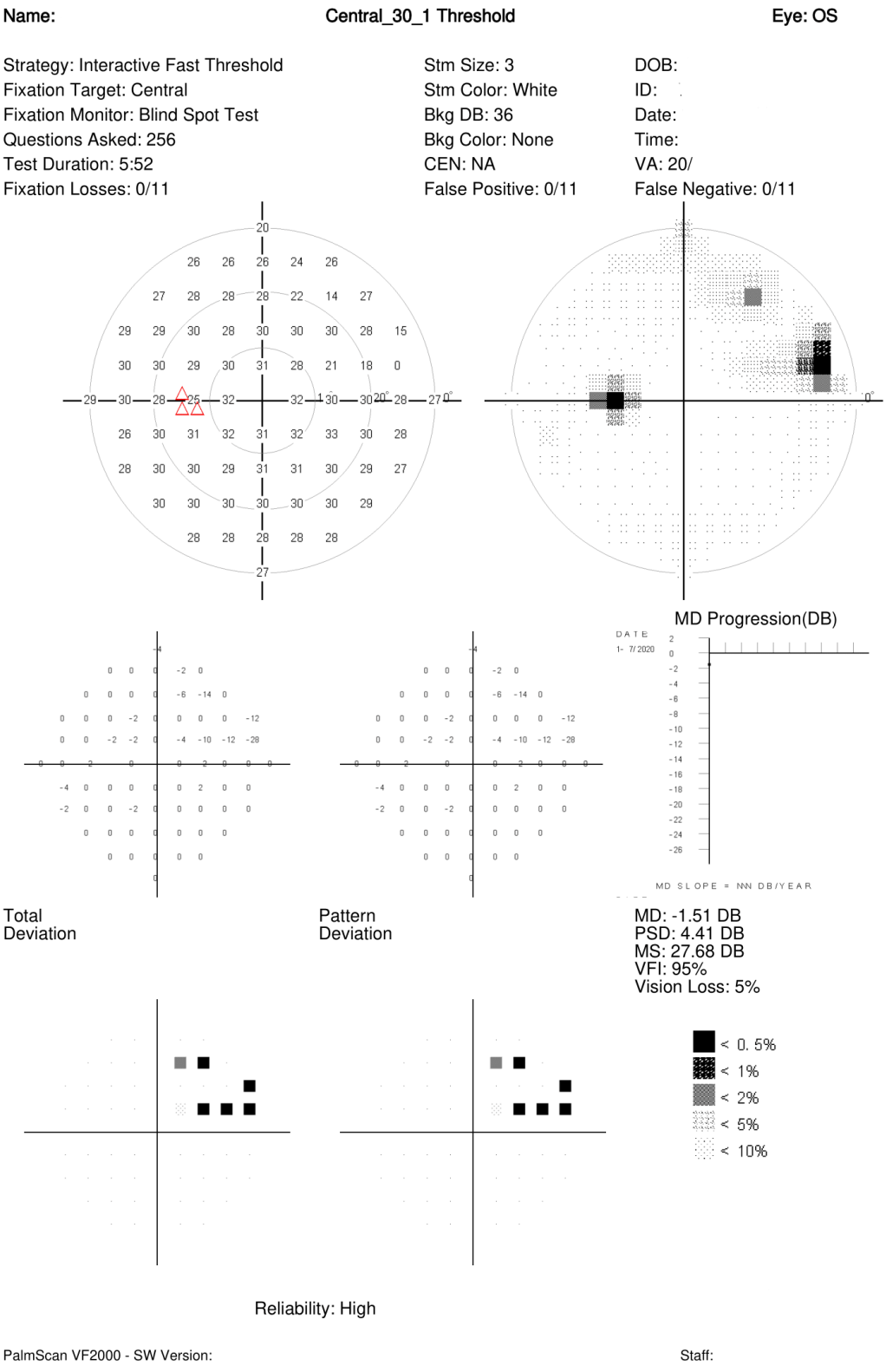


Figure 72: Test Report for Interactive Fast Threshold from Master Central 30_1 Strategy

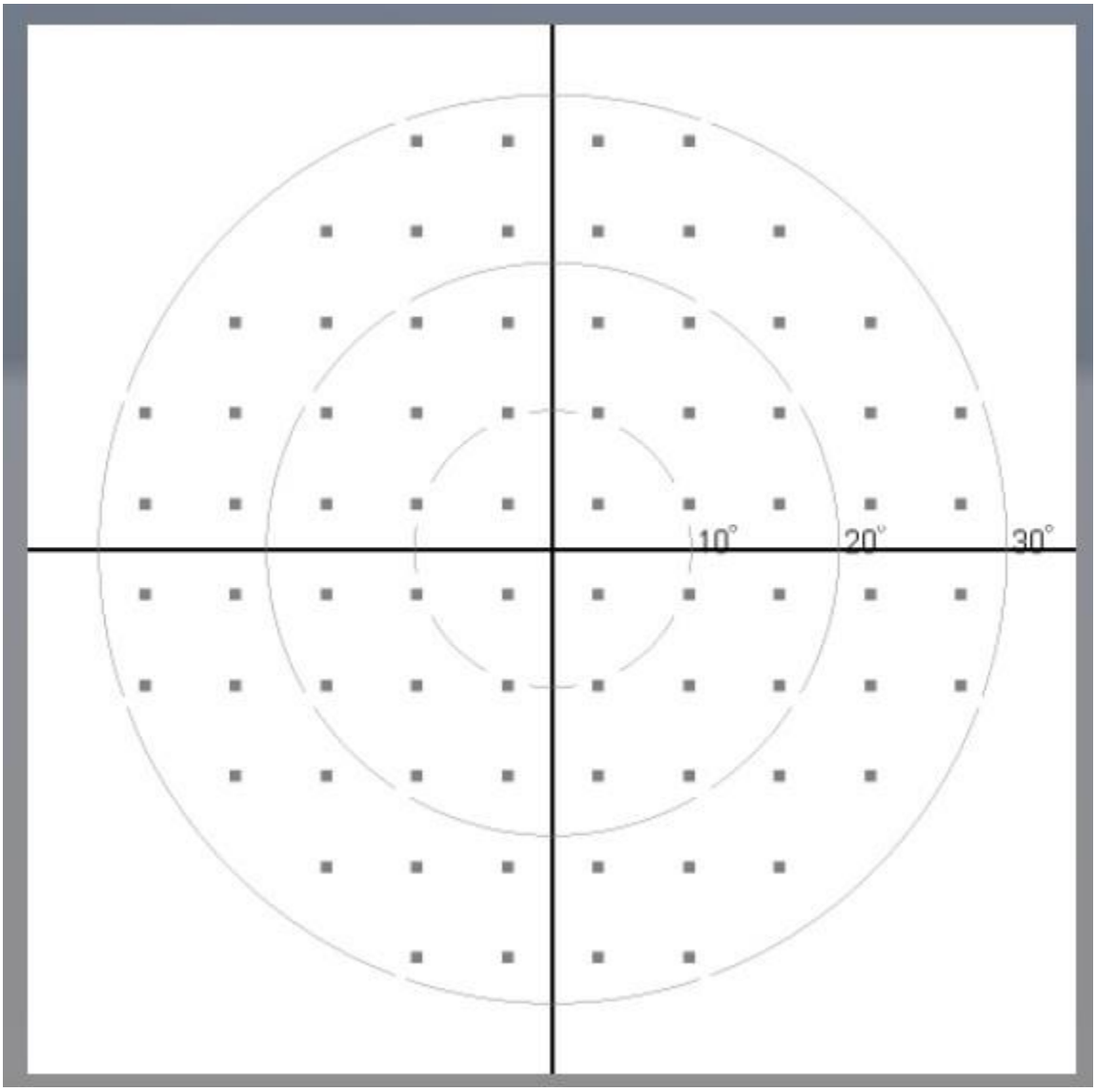


Figure 73: Threshold with Interactive Fast Threshold, Central_30_2 Pattern

The Test shown in **Figure 73: Threshold with Interactive Fast Threshold, Central_30_2 Pattern** is the page displayed for Threshold Test with a strategy of Full Threshold Fast with the Central_30_2 Pattern selection.

Selecting and running the test shown in **Figure 73: Threshold with Interactive Fast Threshold, Central_30_2 Pattern**, will generate a test report as shown in **Figure 74: Test Report for Interactive Fast Threshold from Master Central 30_2** Strategy**.**

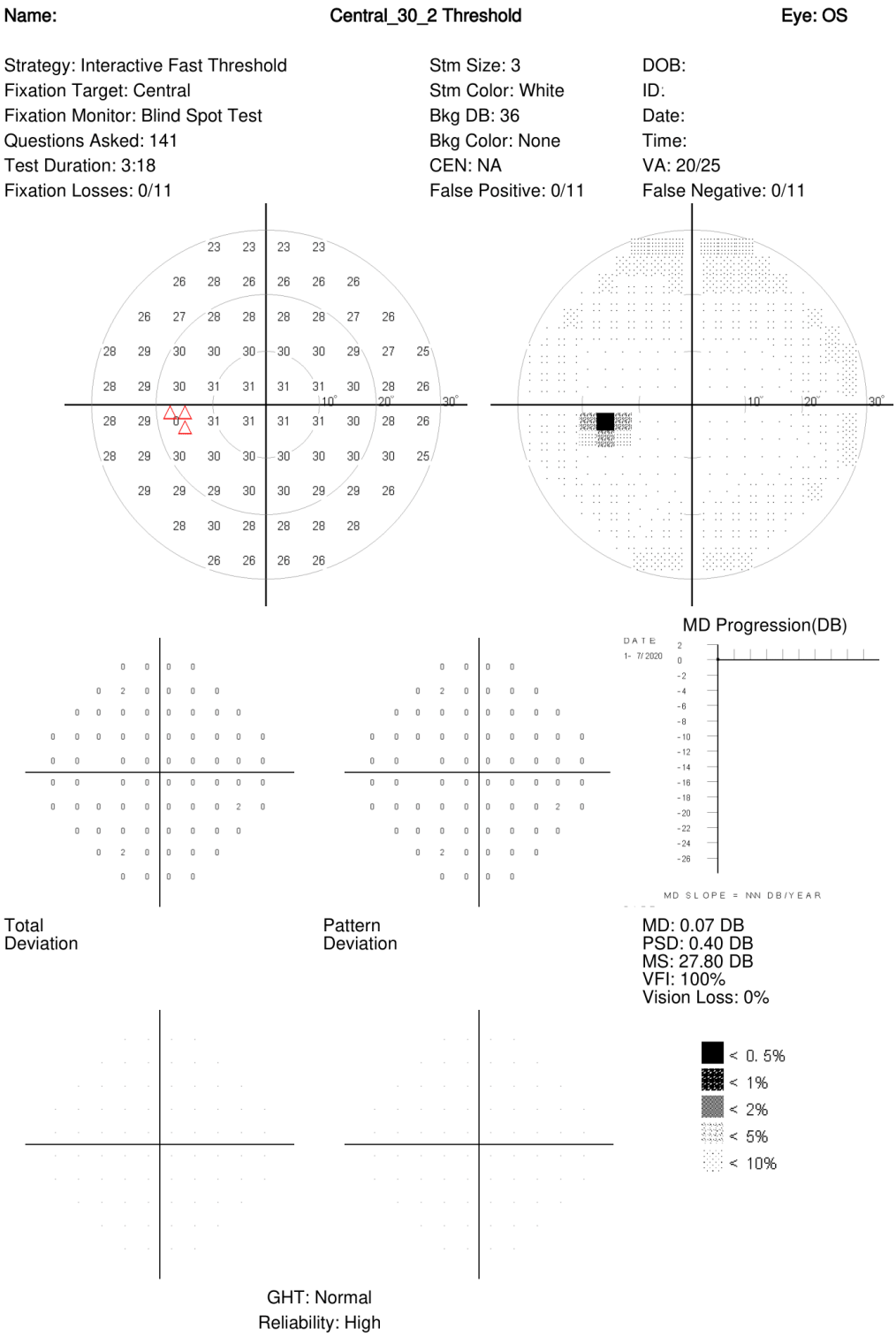


Figure 74: Test Report for Interactive Fast Threshold from Master Central 30_2 Strategy

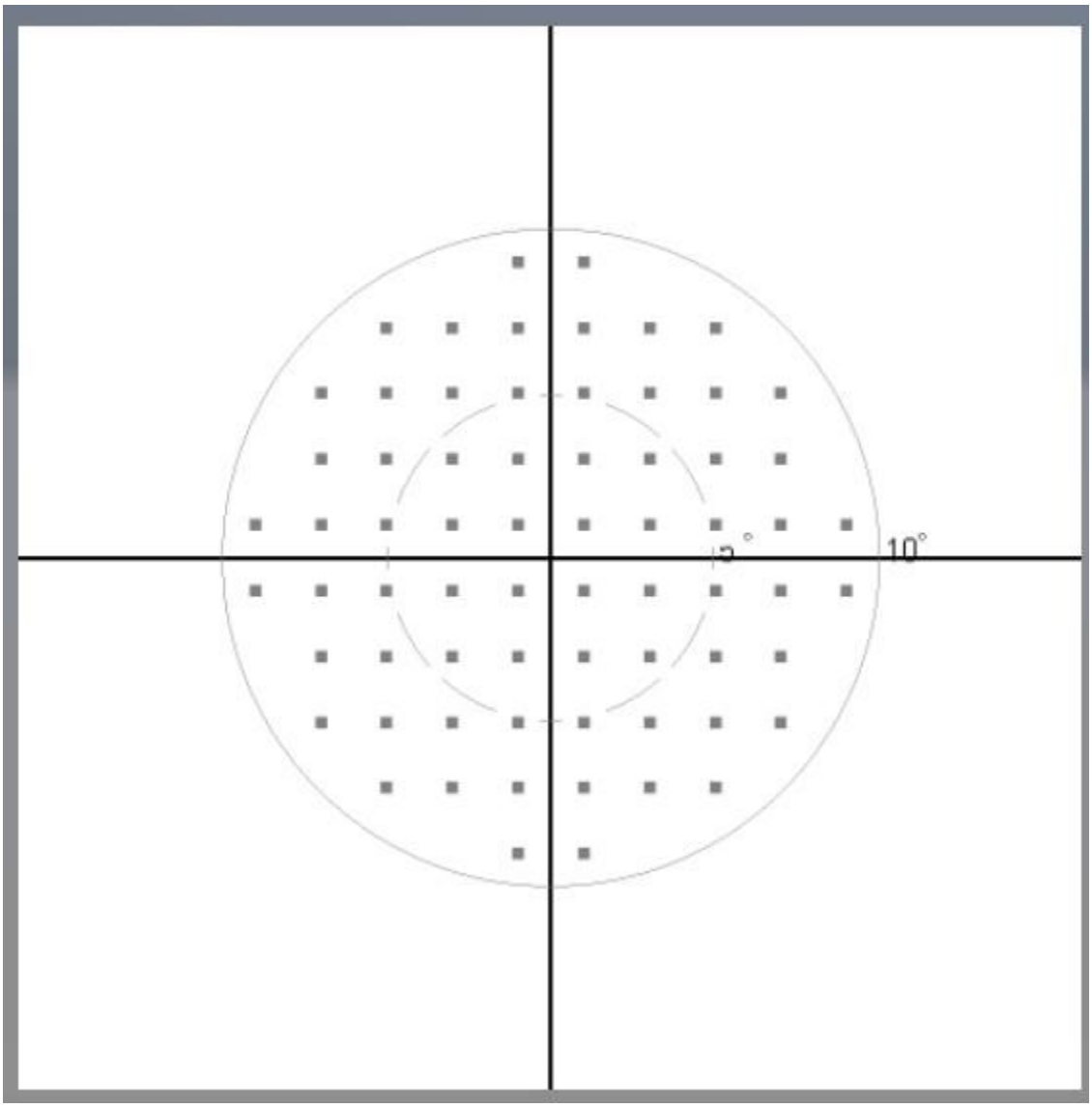


Figure 75: Threshold with Interactive Fast Threshold, Central_10_2 Pattern

The Test shown in Figure 75: Threshold with Interactive Fast Threshold, Central_10_2 Pattern is the page displayed for Threshold Test with a strategy of Interactive Fast Threshold with the Central_10_2 Pattern selection.

Selecting and running the test shown in Figure 75: Threshold with Interactive Fast Threshold, Central_10_2 Pattern, will generate a test report as shown in Figure 76: Test Report for Interactive Fast Threshold from Master Central 10_2 Strategy.

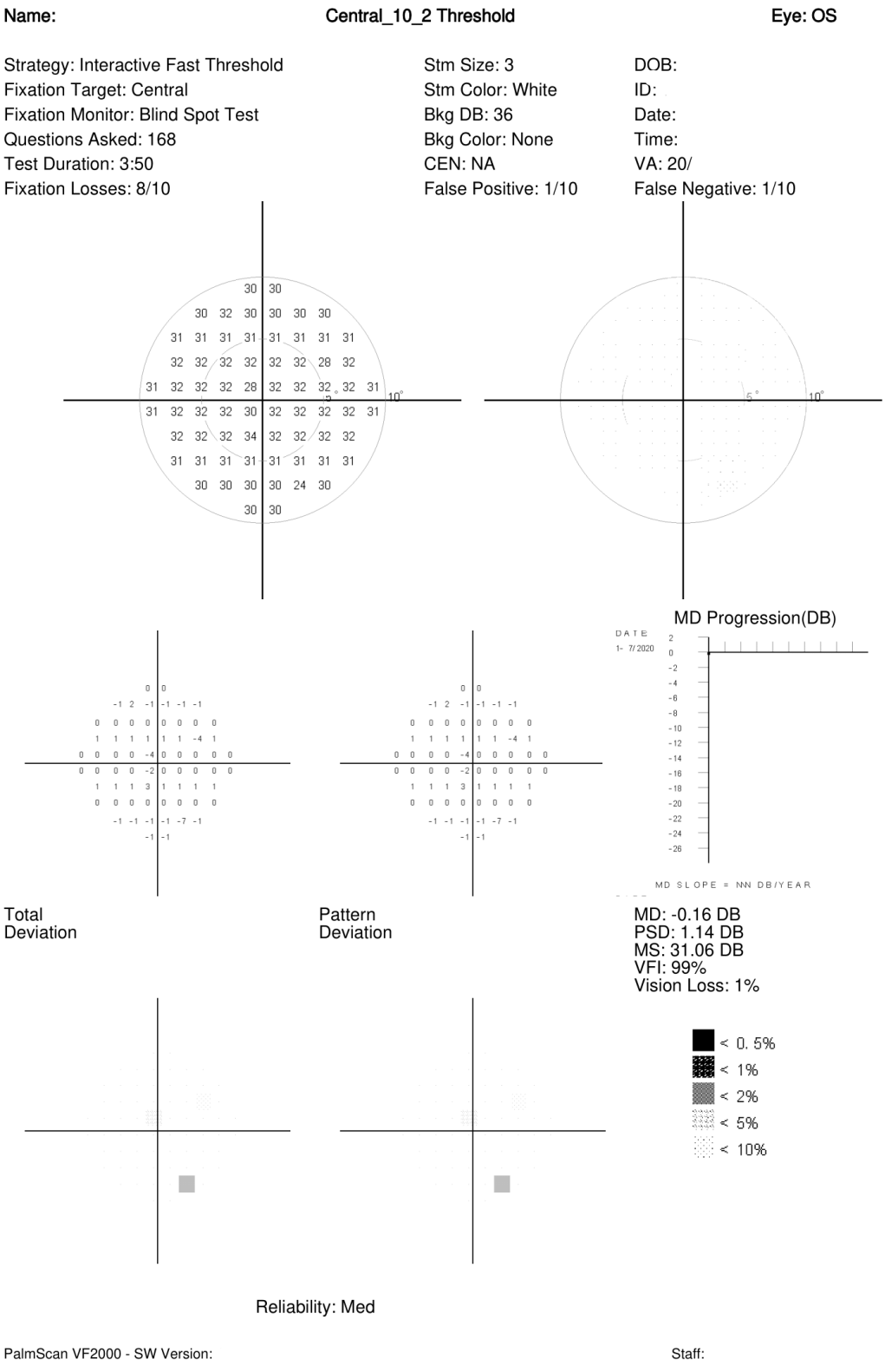


Figure 76: Test Report for Interactive Fast Threshold from Master Central 10_2 Strategy

6.5 Ptosis Test

This test is done to diagnose the extent of defect caused due to an eye droop. An eye droop is a condition wherein the eye lid droops due to trauma, age or other medical conditions. There is two strategies, single intensity, and single intensity fast. Single Intensity strategy means they test any point twice before marking it as a miss, whereas Single Intensity Fast the point only needs to be missed once to register it as a miss. The available patterns are Superior 24-2, Superior 30-2, Superior 50-1, Superior 64.

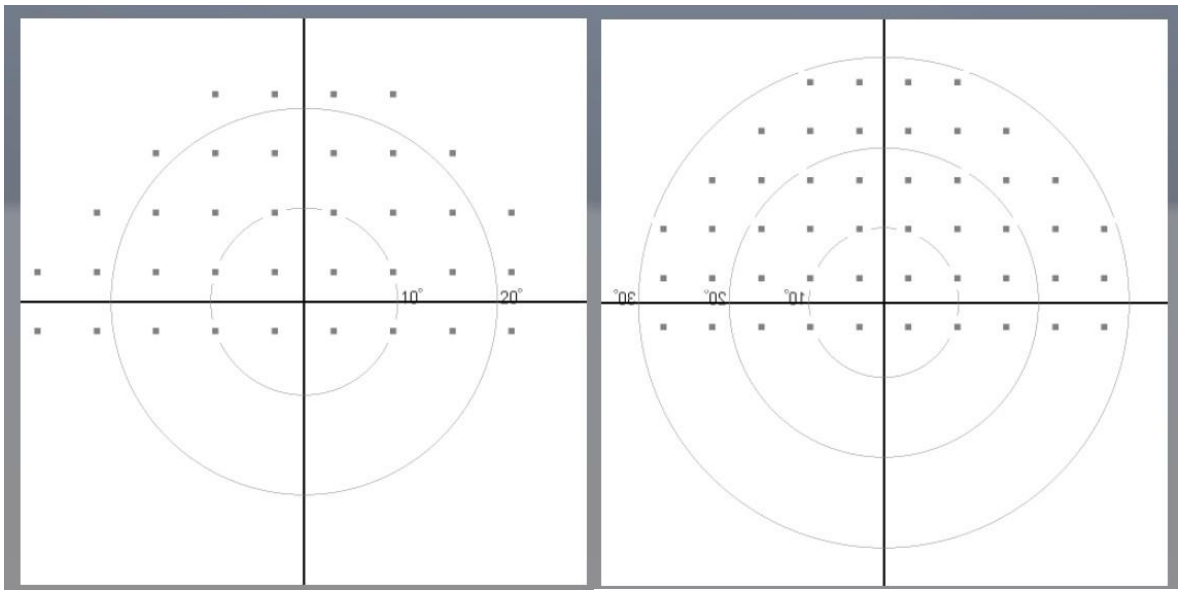


Figure 77: Superior 24-2 Pattern (Left) & Superior 30-2 (Right)

To begin the test, the clicker is pressed. Points of a single preset intensity are shown on the screen. If seen by the patient, the clicker is pressed and the point in the chart is marked green. If not seen, the point is shown again and if still not seen, it is marked red on the chart. By evaluating the chart, the extent of damage due to Ptosis is observed.

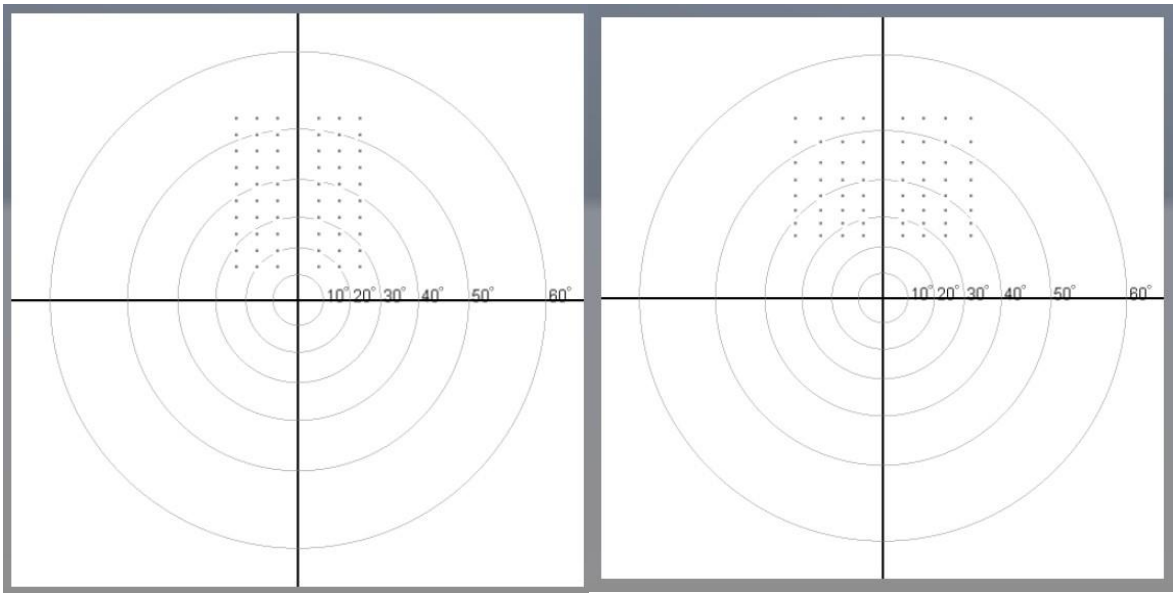


Figure 78: Superior 50-1 (Left) & Superior 64 (Right)

6.6 Neuro Test

This is a screening test which employs 3 different strategies. The 3 strategies used here are Neruo_20, Neuro_35, and Neuro 120 Full Field. This test is specifically designed to test neurological disorders. For example, the test checks longitudinal vision to check brain activity. The strategies are the same as the screening. To get more information, please go to chapter 6.1.1 to 6.1.4.

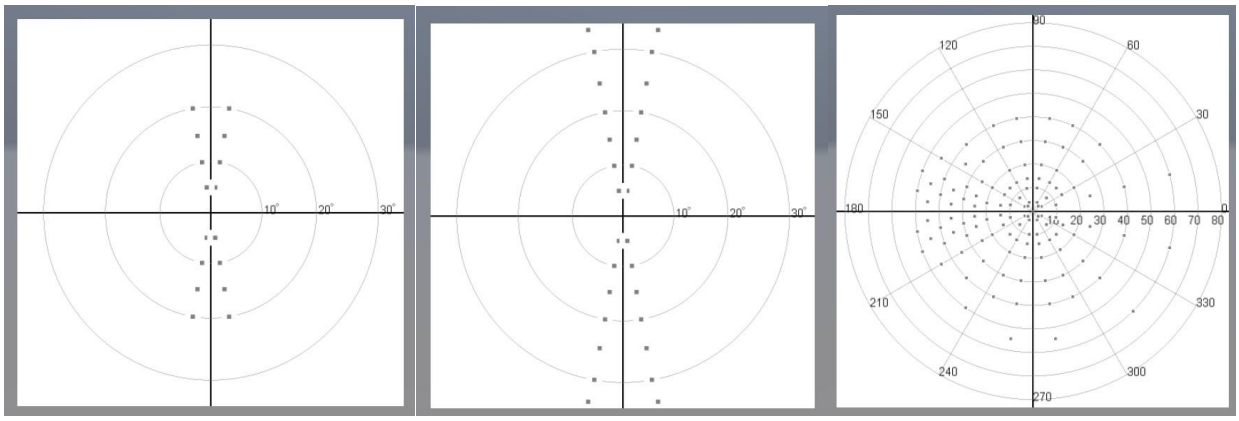


Figure 79: Neuro Point Patterns; Neuro 20 (Left), Neuro 35 (middle), & Neuro 120 Full Field (Right)

WARNING: Do not allow patient to stand up immediately after the test and allow for 2 minutes of recovery after the completion of the test.

6.7 Kinetic Test

Kinetic Tests are a type of test that avoids flashing lights. It is very similar to the Goldmann's test. This test is useful if your patients have epilepsy or sensitivity to flashing lights. First, we will test for the patient reaction time. A light will flash and the time it takes to respond is saved. The average of 3 flashes is then saved as the reaction time. A single test light point comes in from off the screen and towards the center. The patient is either focused on the center (30-) or the opposite side of the test light coming in (60-). When the patient responds, the point is saved. There are 16 test light points or 28 test light points depending on the test (30-16 is a focus on the center and 16 test light points).

There is also a ptosis kinetic test called the 9-point and 9-point auto. There will be a reaction test first. The 9-point ptosis will bring 9 test light points from off the screen on the top hemisphere. Those points are recorded and then is graphed onto the axis and connected with lines. The 9-point auto is the same expect it preforms the test twice. First with the eye not taped, then with the eye taped. Those are both graphed on the same axis and a mathematical calculation is done to see how much of a percentage the eye is blocked due to the area in between the two tests.

6.8 Sophisticated Data

The VF2000NEO Device's statistical software provides immediate expert analysis of visual field test results. It can analyze test results at the time of examination, store test results and analyze them at a later convenient time. It can also recall previously stored tests to analyze for comparative purposes.

This package includes several exclusive features to help identify visual field change:

- Using results from a single test, it can point out suspicious areas that otherwise might not be evident until subsequent tests were done.
- The statistical software can identify areas that look suspicious but compare favorably with normal data.
- Using results from a series of tests, it provides a highly sensitive and informative analysis of changes in the patient's visual field over time.
- The Glaucoma Hemifield Test (GHT) compares points in the superior and inferior hemifields to provide a plain language analysis of test results.
- The VF2000NEO Device provides separate, clinically validated, age-normative databases for analysis. These include databases in addition to the original databases for Full Threshold test results.

6.9 Other types of testing

Blue-Yellow perimetry is also known as Short-Wavelength Automated Perimetry, (available with the VF2000NEO Device). It has performed better than standard computerized perimetry for the early detection of glaucomatous changes, according to published longitudinal studies.

The VF2000NEO Device also offers testing with other colors. By default, the stimulus would be white. Although, healthcare providers can also choose other colors such as red, blue and green provided with the VF2000NEO Device. The available options for background color (Wall color) on which the stimulus would be incident, are black and yellow. Most commonly, the default setting of black background with white stimulus may be used.

6.10 Targeted Fixation

The VF2000NEO Device employs targeted fixation methods for ensuring that patients maintain proper fixation of the target during testing.

7. Additional Resources

Micro Medical Device Inc.'s Interactive Fast Threshold testing strategies allow precise visual field measurements with unprecedented speed. Interactive Fast Threshold is a rapid, reliable, state-of-the-art auto-perimetric technology that is available only with the Micro Medical Inc. Field Analyzer. With the Interactive Fast Threshold strategies, users can obtain visual field information in half the time it takes using conventional testing algorithms without compromising accuracy.

7.1 Data Protection Features

Visual field results need to be saved and protected for future use. The VF2000NEO Device offers a number of data storage methods to file the results. The generated reports can be automatically sent to our secure cloud server for storage. The files can also be transferred manually using Wi-Fi, Bluetooth or USB connections.

7.2 Networking Features

VF2000NEO Device perimeter offers many useful networking capabilities for patient data, test data, and image files. These include:

- Export patient data, test results files (PDF) to a file server
- Synchronize databases on two or more VF2000NEO perimeter Devices via archiving and retrieval
- Back up patient data and test results to a file server for safe external storage
- Restore patient data and test results from a network file server to a VF2000NEO Device

7.3 Information on the Internet

New information about your VF2000NEO Device may be found on the Micro Medical Device Inc. web site. The internet address is: www.micromedinc.com

7.4 Additional components

The following additional components can be connected:

- Printer
- USB Storage Device
- Monitor